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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91215699
Party	Defendant Holaira, Inc.
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Date	11/16/2015
Attachments	Non-Confidential Transcript (FULL) of Trial Testimony of Dr. Dennis Wahr.pdf(222505 bytes) Executed Errata Sheet of Transcript of Trial Testimony of Dr. Dennis Wahr.pdf(71683 bytes) Non-Confidential Transcript (CONDENSED) of Trial Testimony of Dr. Dennis Wahr.pdf(171914 bytes) Exhibit 3 (Non-Confidential) to Dr. Wahr Transcript.pdf(289725 bytes) Exhibit 4 (Non-Confidential) to Dr. Wahr Transcript.pdf(73738 bytes) Exhibit 5 (Non-Confidential) to Dr. Wahr Transcript.pdf(825234 bytes) Exhibit 6 (Non-Confidential) to Dr. Wahr Transcript.pdf(61712 bytes) Exhibit 7 (Non-Confidential) to Dr. Wahr Transcript.pdf(607094 bytes) Exhibit 8 (Non-Confidential) to Dr. Wahr Transcript.pdf(2785543 bytes) Affidavits of Service 7-28-15 and 11-16-15.pdf(91074 bytes)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

- -

Boston Scientific Corporation and
Asthmatx, Inc.,
Opposers, Opposition No. 91215699
and
Holaira, Inc.,
Applicant.

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DEPOSITION OF
DR. DENNIS WAHR

- -

Taken July 2nd th, 2015 By Alexis Jensen

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I N D E X

INDEX OF EXHIBITS

PREVIOUSLY-MARKED EXHIBITS REFERRED TO:
(NONE)

THE DEPOSITION OF DR. DENNIS WAHR, is taken on this 2nd day of July, 2015, at Oppenheimer, Wolff & Donnelly, LLP, Campbell Mithun Tower, Suite 2000, Minneapolis, Minnesota, commencing at 9:07 a.m.

DR. DENNIS WAHR, having been called as a witness, being duly sworn, testified as follows:

EXAMINATION

BY MR. HANSEN:

Q. Good morning, Dr. Wahr. I'd like to start out today by just having a little bit of a discussion about your background, okay?

A. Okay.

Q. Let's start with your education, starting with college, and if you would, take me through to your highest professional degree or certification.

A. Okay. I went -- I went undergrad college to a small liberal arts school in Michigan called Albion College, A-L-B-I-O-N. Then I went to medical school at Wayne State University in Detroit, and then did my internal medicine residency, three years, at

the University of Michigan. Then I did my cardiology fellowship at the University of California, San Francisco, went to UCSF, three years there, where I became an interventional cardiologist.

I spent one year on faculty there at UCSF. Then I went back to Michigan, where I practiced cardiology for about 12 years at -- you know, in Ann Arbor, where I was in private practice at St. Joseph Mercy Hospital and was a clinical professor of cardiology at the University of Michigan.

Then I took a leave of absence for one year to come to Minneapolis and -- and become a medical device entrepreneur. I started my own medical device company, and that was in the year 2001, and since -- and never went back. I never went back and practiced -- I took a one-year sabbatical and never went back.

Q. When?

A. And have been here ever since, for the last 15 years.

Q. Were you a Board-certified interventional cardiologist?

A. Yes, yes, I was what they called triple Board-certified. You know, I was Board-certified in internal medicine. I was Board-certified in cardiology and Board-certified in interventional cardiology; all three different levels of Board certification.

Q. Okay. What's the -- what's the difference between cardiology and interventional cardiology?

A. Cardiologists do -- there's probably four big divisions of cardiology. There's interventional cardiology; there's electrophysiology; there's diagnostic cardiology, which would be things like echocardiographies and MRI scans, you know, they're almost like radiologists; and then there's intensive care cardiology, you know, working in ICUs and things like that.

And they all have their separate Boards, so, you know, it just keeps getting more and more subspecialized. So, a cardiologist is kind of a generalist of cardiology, and, you know, now there's these four subspecialties of cardiology.

Q. Okay.
A. It's pretty amazing. It's pretty ridiculous.
Q. What -- what does an interventional cardiologist do? Can you just describe that?
A. Yeah, interventional cardiology is the part of cardiology that does procedures on patients, you know, and that's really the first thing they started doing were angioplasties. You know, in the mid '80s, that really was origin of interventional cardiology, fixing blocked arteries, working through a pinhole.

That was the beginning of interventional cardiology, the field of interventional cardiology, but now it's gradually expanded to where interventional cardiologists do many different types of procedures, all minimally -- from a minimally-invasive approach. That's really what defines it.

Q. When you were practicing as an interventional cardiologist, did you use medical devices?

A. Absolutely, yeah.
Q. What -- what sorts of medical devices?
A. Well, certainly balloon angioplasty catheters; stents, you know, the wire mesh cylinders that we put in to scaffold open blood vessels; atherectomy devices, which is where you go in and carve out the plaque, you know, and remove it; closure devices, you know, where you go through pinholes to close defects in the heart, you know, holes between to atria and the ventricles, and congenital abnormalities that are repaired now through pinholes.

All of these things replaced the need to have to have open-chest surgery. And now, of course, the -- another big one are the -- literally the percutaneous valves. I mean, literally replacing valves just through pinholes. I mean, those would be the major areas of interventional cardiology.

Q. Turning now to the entrepreneurial aspect of your background.

In 2001, you mentioned that you started --

A. Yes.
Q. -- a medical device company.
What medical device company was that?
A. It was called Velocimed, V-E-L-O-C-I-M-E-D.
Q. What types of product or products did --
A. We made --
Q. -- Velocimed make?
A. We made three different medical products. One was what's called an -- and at the time this was really the first one. It's something called an embolic protection device.
One of the risks of doing angioplasty was sometimes you could go in, inflate a balloon to dilate an artery, but debris could break off and go downstream, you know, and if that happened, you could have damage downstream. Like if that would break off and go to an important place, like the brain or the kidney or something like that, that was one of the areas of complications.
So, we created a little basket that could catch that that we'd put in first and

then did the angioplasty, and if anything went down, you would catch it.

Second product was something called a PFO closure device, which was an umbrella -- a little umbrella, miniature umbrella, that you could put through a pinhole and go in and close a hole between the right and left atrium of the heart.

And the third one was what we called a navigation catheter, because one of the things that would start cardiologists from being able to do a procedure is if they couldn't get to that spot, you know, through the curving blood vessels. So, we made a catheter that could be, using a joystick, directed to go around sharp curves.

St. Jude bought all three of those products in the year -- I started the company in 2001. St. Jude bought that company in 2005, and all three products are still -- are still being sold around the world today. That was the first company.

Q. Were those products approved for sale by the FDA?

A. All of them eventually achieved worldwide

approval, including US.

Q. And what -- are you aware that the FDA classifies medical devices in one of three separate classes?

A. Yes.

Q. And what -- what class of device were the three devices sold by or created by Velocimed?

A. Well, the embolic protection device and the PFO closure device were Class 3 devices. The three classes are, you know, literally 1, 2, 3, where 3 is the -- the highest level of sophistication, and, therefore -- you know, or potential risk and the most novel, which then means it needs the most testing.

Class 1 devices are typically devices that are the least amount of risk, and they're often -- they are often devices that are copies of other devices that are out there, that have predicates, and everything's known about them, and it's just kind of like one more copy doing the copycat thing. You know, they can get a label as a Class 1. Label 2 is somewhere in between.

The navigation device was Class 2.

Q. Got it.
A. But then my second company Lutonix, L-U-T-O-N-I-X, that was a Class 3 device too.
Q. When did -- did you found Lutonix?
A. I founded both of these companies.
Q. And when -- when did Lutonix come into being?
A. 2007, and CR Bard bought that company in 2000 -- in December of 2011.
Q. What product did Lutonix create?
A. We made an angioplasty balloon that had a drug coating on it, and so, when you did the -- so, when you would do the angioplasty, the drug would transfer to the blood vessel wall, and the drug would then prevent the artery from re-narrowing, you know, after you did the angioplasty.
Q. Is that angioplasty balloon approved by the FDA?
A. Yes.
Q. And you mentioned that it was a Class 3 device?
A. 3, yep. First -- first drug-coated angioplasty balloon in the world to be

approved by the FDA. We got approval in 2012.

Q. Where are you currently employed Dr. Wahr?

A. Holaira, H-O-L-A-I-R-A.

Q. And when did you join that company?

A. I joined it in September of 2012.

Q. Did you found that company as well?

A. No.

Q. Who founded Holaira?

A. An individual called Marty Mayse, and co-founded along with another person, an engineer named Steve Dimmer. They were co-founders.

Q. When you joined the company in 2012, was it called Holaira?

A. No, the company was originally founded in 2008. That's when Marty Mayse and Steve Dimmer founded the company. So, when I joined the company, it was already four years old, and the original name of the company was InterventionalPulmonarySolutions [sic], all one word. They -- they called it IPS for short, to abbreviate it.

Q. Let's talk about the Holaira -- well, actually, I should first ask you: What's

your role at Holaira? What do you do there?
A. I'm the CEO.
Q. And have you always been the CEO?
A. Yeah -- well, since they hired me, yeah, for the last three years, yeah.
Q. Okay. Let's talk about the -- the products that Holaira creates.
What -- what is the product that Holaira creates?
A. We -- we have a product that's called -- the name of the product is dNerva, and what it is is it's a -- we use it to do a procedure called targeted lung denervation, and the -- and the system that does it we call the Holaira Lung Denervation System.
Q. Can you describe for me what components there are to the Holaira Lung Denervation System?
A. Yes, there are -- there's a -- the system has a console. The console does really three -- three things that are important. It has a -- it's the generator for the energy, you know, RF energy, radio frequency energy, which is the power we use to -- for the therapeutic effect, which I'll describe

in a minute.

It also has the pump in it, because we have to circulate cold water, you know, through the catheter while we do it. It also has a -- so, therefore, it also has a chilling -- a chiller in the console. And then, of course, it has a user interface, you know, which is a software program.

The console runs the dNerva catheter, and the catheter is the active -- you know, is the therapeutic part of the product, and the dNerva catheter is used by an interventional pulmonologist. The interventional pulmonologist takes the dNerva catheter, and he puts it through the working channel of a flexible bronchoscope, you know, and flexible bronchoscopes are something that interventional pulmonologists have used for years.

It's still -- it's a flexible catheter that goes down -- you know, in through your mouth, down the trachea, and they can look around inside the lungs with this, but our catheter goes through the working channel inside that bronchoscope,

and when -- when the interventional pulmonologist puts it down, he can position it in both the right mainstem bronchus first and then the left mainstem bronchus. You can actually do it in either sequence.

That could be -- the working end of the catheter has an electrode on it, which is used to deliver the energy, and when that electrode is positioned correctly inside the right or left main bronchus, the energy can be turned on, so that it delivers thermal energy to the wall of the -- the main right -- the right and left mainstem bronchus that can denature the nerves that go to the lung permanently, so that those nerves are interrupted.

And what's great about that is those nerves are what -- if you -- if you interrupt those nerves, it allows the airways to dilate, open.

Q. Let's just back up for a second.

You -- you referred to something called a bronchus?

A. Yes.

Q. What is the bronchus?

A. Anatomically, your main airway. It comes from your vocal cords. It's called the -- down to -- its first branch point is the trachea, and that's the big airway. You can feel it, you know, right -- right in your throat.

When that comes -- when that gets down into the middle of the chest, it branches into two main -- two large branches, and those are call the right and left mainstem bronchus, and then the mainstem bronchus, in turn, branch into multiple other airways, and then they keep subdividing into -- and goes down into all of the little billions of airways, you know, out in the lungs.

Q. Okay. So, the -- the bronchus -- the mainstem bronchus is outside of the lungs?

A. Yes, you're not technically in the lungs yet.

Q. Okay. And then the bronchus stems out from the mainstem bronchus and goes into the lung fields?

A. Yeah, it goes -- it goes -- basically, you have the mainstem bronchus, and then you

have secondary bronchi and then tertiary. You know, it's just dividing and dividing and dividing.

Q. And describe for me, again, where the -- where within in the body the dNerva catheter is used?

A. In the right and left mainstem bronchus, in just those first major divisions.

Q. Okay.

A. It never goes down into the lung fields.

Q. And the -- what -- what condition is Holaira seeking approval from the FDA to treat with this device?

A. Well, COPD, Chronic Obstructive Pulmonary Disease, is the disease process, and in patients that have COPD, COPD is characterized by overactive nerves, you know, that -- that are causing -- and these overactive nerves cause the airways to be constricted, you know, kind of in spasms, so to speak, and up until this point in time, the way COPD patients have been treated are with inhalers.

And, of course, you see this on television all the time. Spiriva is the

leading selling pulmonary drug in the world, maybe the first or second leading selling drug of any kind in the world. You know, the inhaler that you see people who can't breathe puff on.

And what that -- the way that inhaler works, it goes down, and it literally is trying to block the nerves, you know, that go to the lungs so the airways can open up. What we're trying to do, we're going in, and we're -- by using this RF energy and the right and left mainstem bronchus, we're trying to ablate those nerves, so that we -- so that we can permanently -- get a permanent dilation, so that you have a permanent bronchodilation. So, it would become an alternative therapy to drugs or even an additive, where we actually know it would be an additive to drugs, and there's a reason for that, to benefit.

Q. Let's talk about the -- a little bit more about the medical procedure in which the Holaira Lung Denervation System is used.

You mentioned a name for the

medical procedure itself. What was that again?

A. Targeted lung denervation.

Q. Okay. And where is targeted lung denervation performed? Like in what kind of setting?

A. It's in a hospital, a pulmonology procedure room. It's in a special room that -- where hospitals do these bronchoscopies procedures.

Q. What -- who performs the procedure?

A. An interventional pulmonologist.

Q. What's an interventional pulmonologist?

A. Well, it goes -- it kind of goes back to the same thing about when I talked about interventional cardiologist.

Until recently, until literally a couple years ago, the -- the highest level of certification within the field of pulmonary was a Board-certified pulmonologist, and these were doctors that did bronchoscopies, you know, just that were diagnostic, you would go and look around to see what was in the lungs.

But in the last -- over the last

number of few years, similar to what had happened 15 or 20 years ago in cardiology, a new field has arisen of interventional pulmonology, where pulmonologists can do additional training to become skilled at actually doing invasive procedures, and this group are what we refer to as the interventional pulmonologists, and to be -- and that is a fully now recognized Board certification-required subspecialty of pulmonology, where they literally have to do a two-year fellowship after training all the previous stuff, do two additional years of interventional pulmonology and then pass the Boards to be a card-carrying credentialed interventional pulmonologist, and they -- they do everything -- well, I shouldn't say they do everything.

They do an awful lot. They do a lot of different procedures now just through the bronchoscope that used to require open-chest surgery. You know, the same story again like what happened 20 years ago in cardiology, and they'll do everything from putting in stents to dilating blocked

airways to resecting tumors to, you know, removing foreign bodies, just lots of things.

So, we as a -- our procedure, targeted lung denervation, is one of an array of things that they do.

Q. You mentioned that -- how many of -- roughly how many interventional pulmonologists are there in the United States, if you know?

A. Today, there are about 150 roughly, about 150. So, you can kind of think of it as each state -- if all states were average size, there would be two or three in a state.

It will grow. You know, the -- the fellowship programs that train them are turning out about, you know, seven or eight new ones a year, you know, in the US, you know, the specialized places that are formally training them. So, that number will -- I expect will slowly grow.

Q. Okay. Let's discuss a little bit how the company changed names from IPS to Holaira, and to assist with the -- the discussion, I'll mark and hand you an exhibit.

A. Sure.

(Exhibit Number 1 was marked.)

BY MR. HANSEN:

Q. Dr. Wahr, you've been handed what's been marked as Wahr Exhibit 1.

Do you recognize this document?

A. Yes.

Q. What is it?

A. This is -- these are documents that we put together not long after I took over as CEO to help guide, you know, our renaming process, you know, and also, you know, some Board presentations that -- where we actually conveyed some of this information to our Board of Directors --

Q. Okay.

A. -- about why we were doing it.

Q. And was this a presentation present to the Holaira Board of Directors?

A. Yes, this first one here, the open session of the Board meeting. I mean, this was part of the Board meeting where -- you know, Board meetings have generally two parts.

They have what's called an open session, where key company executives are

included; and then there's what's called a closed, where it's just me with the Board of Directors period. You know, that's the part where you talk about things like compensation and confidential stuff that you wouldn't want to have other people sitting in on.

Q. During the --

A. Open session.

Q. -- open session, if you'd flip to page -- the twelfth slide in, which is -- has the Bates number on the bottom right, Holaira 627?

A. Yep.

Q. There is a -- appears to be a discussion about branding activities?

A. Yep -- yes.

Q. What was the purpose of this -- the inclusion of this slide in the presentation?

A. Well, I was -- I introduced it -- as you noticed on the first page, the company was still called Innovative Pulmonary Solutions at this time, but I wanted to -- and I -- this -- this was really my first Board meeting, you know, because I was hired in

September, and this was December, and so, this was my very first Board meeting that I led, and I had already decided by that point that I wanted to change the name of the company, and this was my starting to socialize that concept to the Board.

Now, you have to realize this was a Board of Directors that had been with this company for four years, you know, and so, they were pretty -- you know, they were very familiarized with the previous name, and so, I just didn't want to come in and say I'm changing, so how I'll commonly do things is I'll introduce something and socialize it and then -- then come back with a recommendation at the next Board meeting.

It's a good way to run a company, by the way, if you ever do this. Don't blind-side your Board with just radical stuff in the cold.

So, this was socializing the concept that I was working my way towards rebranding the company, which is a way of saying, we're going to change the name, we're going to change the Website. You

know, we're going to -- you know, our materials that are shown publicly, you know, we're going to rethink.

Q. Why did you want to move away from the IPS name?

A. Well, this was my third time around the track, you know, with a company, and so, while I don't consider myself a marketing person, I'm used to working with marketing people, and I do believe what they say.

And, to me, there were a couple -- there was a few problems with Innovative Pulmonary Solutions.

Q. What were those problems?

A. Well, one is -- is that marketing people will tell you that they really -- they would never recommend the name of a company that goes much more than two or three syllables. Innovative Pulmonary Solution had 11. It's too many words, you know, to be efficient, you know.

And the second thing is is that it was so long that you couldn't even fit it into some URL boxes. You know, when you go to type in your emails and stuff, it

wouldn't fit, and, you know, you'd run out of space, and then you were just stuck on a lot of forms. I found that particularly irritating.

The third thing was it was just kind of a sentence. You know, it wasn't really a unique word. Marketing people and branding people want you to create your own unique word. Because it wouldn't fit into URL addresses, the company started calling itself IPS for short, which is a three-letter acronym, but the problem with IPS was, one thing, marketing people don't like acronyms, but, number two, it was already trademark. I mean, in fact, it's trademarked by about 15 people worldwide for all kinds of different things. There's absolutely nothing unique about IPS, you know, as a three-letter thing -- thing out there.

So -- so, for all of those reasons, I felt we needed -- and since the company -- I had just become the new CEO, part of becoming the new CEO was we were going to move the company -- we decided we'd move the

company from Seattle, where it had been the first four years, to Minneapolis.

So, we were moving the company, and it's going to be a new entity, you know, here in Minneapolis, of which the people in Minneapolis didn't even know -- you know, there was no memory of the old name. So, it was the perfect time to change the name.

Q. On the -- on slide 12, the third bullet point down says: Need image that demonstrates we are different from competition, relevant to the target audiences and credible.

Do you see that?

A. Yep.

Q. What was meant by "demonstrates we are different from competition"?

A. This is a Class 3 device, first time -- and it's very novel, first time anything like this has ever been done in humans. You want a name that is not confused with anything else, you know, that is totally unique, that will -- a new word -- a new word, you know, created that will become the image of your product, you know, that no physician will

ever find confusing.

You know, that's fundamental -- that's what's fundamental. You don't -- you know, when the Google people decided to have a -- a search engine that you could find anything on the Internet in 100th of a second, they wanted a word that nobody had seen before, and that's -- they created the word "Google," which now everybody thinks has been around for a century, when, in fact, it's only been around for ten years, because it was brand new. That's what you're trying to do.

Q. After this Board meeting, did the -- did the IPS continue in the process of rebranding?

A. Yes, the Board -- when I introduced this, the Board gave me -- they said, yes, we're interested in having this done, go do it.

Q. And what -- did Holaira, or IPS at the time, retain any third-party entities to assist in that process?

A. Yep, it's on here. You know, I had already started the process, you know, with a marketing consultant named Lorraine Wright on the slide, and Lorraine, in turn, was

working with a marketing company called Six Degrees.

Q. Okay.

A. Lorraine is not an employee of Six Degrees. They are two different things. So, Lorraine is our marketing person basically.

MR. HANSEN: Let's mark that exhibit.

(Exhibit Number 2 was marked.)

BY MR. HANSEN:

Q. Before we get into this next exhibit, Dr. Wahr, you mentioned that Lorraine Wright is not an employee?

A. Right.

Q. Although she's not an employee, is she treated like -- as if she's an employee with respect to her job function?

A. Yes, she's our -- she's our only marketing person we have. She does 100 percent of our marketing activities, which, because we're still a pre-revenue company, clinical stage, as I call it, we don't really have a need yet for a full-time marketing executive.

So -- so, that's why she's still at consultant status. I would estimate she

probably spends about 50 percent of her time working with us, but she has some other clients, but she's our sole person, and she carries a Holaira business card, has a Holaira -- has a Holaira email address, and she -- she is our -- she functions as if she's a full-time employee. All marketing-type questions, you know, that flow through -- or inquiries from the Website flow through her.

Q. Let's turn to Exhibit 2.

A. Okay.

Q. Have you seen Exhibit 2 before, Dr. Wahr?

A. Yes.

Q. What is Exhibit 2?

A. These are the materials that were put together by Six Degrees working with Lorraine Wright that were literally the -- the documents we worked off of in our company meetings as we started through a methodical process of -- of considering various alternatives for renaming the company.

Q. If you turn to the third slide in, which is Bates number Holaira 48, there's a slide

entitled: Naming Considerations?
A. Yes.
Q. The first bullet point says: The new name must be shorter, simpler, fewer syllables.
What is that in reference to?
A. That's in reference to our previous name of Innovative Pulmonary Solutions that had 11 syllables.
Q. Okay. If you turn to Holaira 50, which is another couple of slides in, it's entitled: Metrics for Naming?
A. Yep.
Q. Can you describe what the purpose of this slide is?
A. Yes, this is a -- this was a slide that Six Degrees put together. I would say that it's pretty much a boilerplate that marketing firms use for how you -- you know, it was not unique to us. It was unique to what they do every time regardless of the client, in terms of, when you start through, how do you invent a new name or new word.
By the way, this is kind of -- I found this -- found this fascinating when I got into this. There is no word in

Webster's Dictionary that's not trademarked. So, you can't name the company anything of a word that exists. There -- whatever the thousands of words, they're all trademarked.

So, the only way you can create a new trademark is to come up with a brand new word. Isn't that amazing? There are more trademarks, in fact, than there are words in the dictionary. So, you have to -- I thought that was pretty -- pretty amazing, you know, which is why you've got to get creative people to do this stuff.

Now -- now, but these things here are -- are what they say are -- are the different categories of how you think about it, you know, as you go about it as a team, you know, association, different, clear, pronounceable, memorable --

(Reporter clarification.)

THE WITNESS: The categories were product association, different, clear, pronounceable, memorable, positive and available. All the categories that you needed to -- you had to be able to have all of these apply at the end of the day.

BY MR. HANSEN:

Q. And we may have discussed this already, but why was it important -- why was it an important metric for the name to be different from the competition?

A. Because we had -- we have a novel, first-in-the-world-ever-done product. We want -- we wanted no confusion that this had any similarity to anything else. It had to be totally unique, the word, to imply the fact that this also was a totally unique product.

Q. If you turn to the slide just before the one that we're on, there's an identification of a number of products that treat pulmonary conditions, correct?

A. Yes.

Q. Why were you considering these other entities and names in this process?

A. Because we knew that these were names of products that interventional cardiologists were already familiar with and using, and we wanted to make sure that ours was -- you know, was not similar to any of them. I mean, again, getting back to the different

and unique category.
Q. I think you said interventional cardiologists --
A. Oh, did I say that?
Q. -- do you mean pulmonologists?
A. I continue to do that, because I used to be one, but, yeah, interventional pulmonologists. Glad Marty isn't here.
Q. If you turn to slide Holaira 56, it's entitled: Naming Categories?
A. Yeah -- yes.
Q. Can you describe for me what -- what this slide reflects and what these naming categories mean?
A. Well, the way the marketing team helps stimulate growth -- I mean, group-think is to provide categories, you know, of concepts, and they generally name, when they -- you know, in doing this, they come up with anatomic things or physiologic things or structures, you know, that are -- that have something to do with what you're doing, you know, and so, therefore, in terms of what we do, it's -- it's pretty easy for them to go nerve, air, pulmonary, lung,

respiration, open -- you know, "open" meaning open airway.

So -- and then they -- and then you take each of those one by one and start to create words that might be related or convey or be related to these general categories.

Q. So, for example, air-centric?

A. Yes.

Q. What -- what impact does a word being air-centric have on the word itself?

A. Well, I mean, each of these would -- would commonly -- you know, would -- you work around that. You start with that concept of, say, air, and then you work around it and try to mold words, you know, that might encompass it.

Q. Okay. And why -- if you know, why were these specific categories identified as potential categories for words?

A. Because they related -- they all had something to do with our procedure, you know, what we do.

Q. If you turn -- we're going to jump around just a little bit, but if you turn to the third from last page of the slide deck,

which is Holaira 111, there's a short list of names.

Were there more names considered than just this -- this short list?

A. Oh, yes, yeah, yeah. I mean, there were -- yeah, there were many, and in all of those categories, there were a lot in each category.

What these -- what these marketing people do, they sit down and -- and they provide you with a list to stimulate, you know, all various renditions within these categories.

Q. What -- what process was used to take the longer list and winnow it down to the shorter list?

A. We had -- we had a group meeting, where we had -- there were really -- there were really, you know, a smaller group of people, four or five people, that -- that put the most time into this.

It was myself; it was Marty Mayse; it was Steve Dimmer, the other founder; Lorraine Wright, we probably put in relatively more time in discussion, but

there was also a larger group of some of the other employees in the company that were also brought in to comment on -- on just gut reaction, you know -- you know, what kinds of things that started to shake out as people's favorites.

Q. Let's flip back in the slide deck to Holaira 65, which is an air-centric name, and the name is Holaira?

A. Yep.

Q. Ultimately, this is the name that the company selected, right?

A. Yes.

Q. Why did the company select the name Holaira?

A. The -- there were -- there were several reasons that this one, as more and more discussion went, rose to the top, and the one that I liked the best was that the fundamental reason why I think our product is going to be so exciting in the marketplace is because the current standard of care for this disease is -- are these inhalers, these drugs, you know, that people breathe -- breathe in, but what's known by both -- all physicians know this, and the

pharmaceutical companies themselves acknowledge it, is that the Achilles heel of drugs that they don't talk about for treating lung disease is that, when they breathe these drugs in -- and they can only be given by -- by inhalation. They can't be given by swallowing pills, and there's reasons for that pharmacologically, but the drugs will go preferentially into those small airways that are wide open, and they won't go to the ones that are blocked, the drugs.

So, the drugs, it's estimated, achieve only maybe at best 50 percent of the potential benefit that could be had if you had a way to get -- get -- you know, get, in effect, in all of the airways, not just the open ones, but that's also not really known for sure. People debate that.

Some people say it's less even, you know, but -- so, drug therapy is really only treating part of the lung, you know, when these -- when it goes in, but it's still better than nothing.

Our real benefit of our therapy by

going in and denervating the nerves in the right and left mainstem bronchus, and 100 percent of all the nerves that go to the lungs go in -- are in the walls of that right and left mainstem bronchus. By denervating, we could dilate all the airways, the whole thing, the whole lung, and so, I love the concept that we'll be the first company that can truly deliver therapy to the whole lung, you know, and so -- and, whereas, I would say pharmaceuticals deliver therapy to only part of the lung. We're the whole lung.

And so, the whole focus here was on whole, you know, W-H-O-L-E, but the marketing people, being the clever way they are, said, let's spell it H-O-L, because it's pronounced exactly the same way and it's clever. Now, you're looking like a unique word, as opposed to W-H-O-L-E, which is a word that everybody recognizes.

So, shorten it to Hol, H-O-L. So air to the whole lung, and that really started to resonate to people as really a -- a cool thing.

The second thing was that -- was that, as the people started doing reviews, there's very, very few things in all of medicine, you know, whether it's drugs or procedures or -- or words or anything that begin with the letter H. H is really rare. So, it was extremely unique, and the other thing is is that we also found out the word holo, H-O-L-O, is actually another word that you can find out there, and actually its derivation is also whole, you know, actually. So, if you drop the W in -- you know, in languages, H-O-L-O, also means whole. So, it really came through that it was air to the whole lung and -- and really unique.

The one thing that -- that I had a little hesitation about, which actually also makes it -- made it really unique, but was that we struggled with, and when we tested this around with different people, people had -- when they said, what do you think when you see this word? Well, you know, there's a derogatory street slang term called ho, you know, like that person's a

ho.

Anyway, but that is a negative term, and -- and so, we struggled with the fact that it would have too strong, you know, a differential, you know, in terms of a word being thrown into -- into medicine, and so -- but the marketing people actually kind of liked that, because it gave it more of an edge, you know, of uniqueness. And, by the way, nobody really thinks that, you know, as our testing -- they really see "whole," you know, is where they go.

Q. Can you describe for me how the company pronounces its name?

A. Yeah, it's Hol, H-O-L, hyphen, second syllable, is air, A-I-R, and the last syllable is A. Three syllable, where it's H-O-L, then second syllable A-I-R, another syllable A, and we really differentiated -- we really wanted that differentiated all the way to the point that on the -- that, on the logo, we put an umbrella of dots over the word A-I-R to differentiate the word "air" and separate it from the syllable H-O-L, so there was no -- no -- to really call that

out, to get the word Hol on there, H-O-L, and you've seen the -- it's on the business cards. You've seen the logo.

Q. Going back to the -- the short list of -- of names, there were -- at the back of the slide deck, there are a number of names that Holaira ultimately did not go with.

A. What page?

Q. 111?

A. Oh, 111.

Q. Yep. For example -- well, first, let me ask you this: There are a number of names that have Xs in the different columns.

A. Yeah.

Q. Would we take that to mean that the names with Xs are in the running or out of the running?

A. In the running.

Q. Why didn't Holaira end up using the name Vitaira?

A. Well, you know, there were people that liked Vitaira in the group, but -- but one of the things that -- that became a differentiator on that one was that, for whatever reason, and these things tend to go in trends, but

if you look at the last four or five years of medical device company names, there have been a lot of Vs. There's a lot of companies out there that start with V, and so, for that reason, that was a discriminating -- that was probably one of the main reasons why we moved away from that at the end of the day. In discussion, in fact, my first company had begun with a V, Velocimed, and that was a bias to me. I didn't want to do another V company.

Q. And why didn't you select Apaira?

A. Again, I think that it was a -- there are A companies out there, and we thought that -- we thought that there was another company out there called Alero, you know, that we thought that looked a little close to, so we thought Apaira was close to some other competitors.

Q. And when you say "Alero," are you talking about the product sold by Boston Scientific?

A. No.

Q. What --

A. It's a pharma -- it's a pharma drug.

Q. And how do you spell that?

A. A-L-E-R-O, I think is the name of it -- is how it's spelled.
Q. Ultimately, you went with one of the air-centric names, Holaira?
A. Yes.
Q. Why did you go with an air-centric name?
A. It was a category people liked the best. I mean, it is the fundamental basis of what we do is to improve airflow to the lung. I mean, it's -- it's the closest.
Q. Were you aware of any other company name, product names or trademarks, that had the word air within it when you made the decision to go with an air-centric name?
A. Yes, there's a lot -- there's a lot of "airs" out there.
Q. When you say "there's a lot of airs out there," what do you mean?
A. I mean, there's a lot of companies -- I mean, there's a lot of products out there where the syllable A-I-R is a part of the name.
Q. And what -- what field are those products?
MR. WALZ: Objection, foundation.
BY MR. HANSEN:

Q. Do you know -- you mentioned that there's a lot of words out there with "air" in it?
A. Yes.
MR. WALZ: Objection, foundation.
MR. HANSEN: To what?
MR. WALZ: How does he know that there are a lot of products out there that have "air" in it? You can lay the foundation. I don't know how he knows that.
MR. HANSEN: He just testified that he knows it.
MR. WALZ: How do you know it?
BY MR. HANSEN:
Q. Okay. Dr. --
A. I've seen them a pulmonary meetings and generally follow the literature.
Q. Okay. So, you work at a company that has a product -- is developing a product in the pulmonary space, correct?
A. Yes.
Q. And through going to meetings in the pulmonary space, you're aware of other company names?
A. And product names, yeah -- yes.
Q. And is that how you're aware of other --

A. Yes.
Q. -- names using the word "air"?
A. Yes.
Q. And are those other product names that are in your mind in the pulmonary space?
A. Yes.
Q. Can you recall any of them?
A. Xolair.
Q. What does Xolair do?
A. It's a drug.
Q. What -- are you aware of the term "Alair"?
A. Yes.
Q. Sold by Boston Scientific?
A. Yes.
Q. Why -- what consideration, if any, did you take of that name when deciding to choose the name Holaira?
A. Say that again.
MR. WALZ: If I could, you took a piece of paper out of your coat pocket, and you now seem to be referring to it.
THE WITNESS: Yes, there's -- I have four names of companies with "air" in it that I think are really good examples.
MR. WALZ: Okay. That's fine. You

can use it.

THE WITNESS: Okay.

BY MR. HANSEN:

Q. Dr. Wahr, what -- what examples are on that piece of paper?

A. Well, there's Singulair, Xolair, VitalAire and Alere, A-L-E-R-E.

Q. Turning back to my question about Alair, the product sold by Boston Scientific, what consideration, if any, did you take of the existence of that name when deciding to use the name Holaira?

A. We wanted to make sure that we were very different from any other word, and I would say that that fell into that category. You know, we were -- we -- as you saw in the previous slide, we got the list of the other leading -- or I shouldn't say leading, but the known products that are used by interventional pulmonologists, and so, we looked at that entire list and said, are we different than all of these words, you know, and we were -- we were confident we were different from all of these words, because nobody had anything that looked like Hol,

H-O-L, at the beginning of the word.
Q. What -- why did you want to be different from Alair?
A. Because eventually -- because we have a unique product, and we want our -- our physicians, who are our main customers, to -- to have no confusion about what we are doing.
Q. Let's turn to the -- the development of the Holaira products.
I understand, and certainly tell me if I'm wrong, I understand that the Holaira product is not commercially available in the United States?
A. It's a clinical stage company.
Q. When you say "it's a clinical stage company," what do you mean?
A. It's not approved for use, you know, for commercial sale.
Q. And what -- what process is the company undertaking to become approved for commercial sale?
A. We're doing a -- we're working through clinical trials, you know, human clinical trials, and the -- the process that -- that

we're doing is we're doing a three -- three-stage development program, which has began with Phase 1 clinical trials. We finished that.

We're in what are now called Phase 2 clinical trials, and then if our data looks good in the Phase 2 trials, we'll move on to what's called Phase 3 clinical trials, which would be the pivotal trial. We're in the middle of Phase 2 right now.

Q. Why is the company undertaking that process?

A. Well, the product is -- because the product is novel and has never been done before, you need to be very careful, you know, as you work your way through the development process, that you make sure that -- that your product is safe, first of all, and the way that's done in the eyes of the regulatory authorities is they will approve you to treat a small number of patients.

You treat those patients in the Phase 1 trial, and then if that looks good, then they'll give you a larger number of patients you can treat, which is basically Phase 2 trials. If that data looks good,

and basically Phase 1 and -- Phase 1 trials are really focused on safety. You know, they -- the way this works, they first want to know that you're not going to hurt anybody, and then if they -- if you pass that bar, then you move on to where your trials will be big enough that you can start to, in followup testing, show that you're actually beneficial, you know, but safety comes first, and then you move on to the benefit part.

So, Phase 2 kind of attempts to re-corroborate the safety issue of Phase 1 in a large enough pool of patients that you might be able to start to get a signal to understand your -- your efficacy of a mark. The other thing -- the other part about Phase 2 trials is that you also are allowed to start exploring some other parameters, such as dose and, you know, some other variables about your product.

Q. You mentioned --

A. But when you get to Phase 3 -- when you get to Phase 3, you need to have your final procedure and your energy dose and

everything has to be defined and done, and then that's it, and that would be the trial in which eventual approvals are based is Phase 3.

Q. You mentioned earlier that there are three classes of products within the FDA?

A. Right.

Q. What class of product is the Holaira System?

A. It's Class 3, and generally Class 3 products are the products where you would go through this type of extensive clinical testing program.

Class 1 products, for example, may not need any clinical testing at all. I mean, they could literally just -- in humans, they could just be developed on a benchtop somewhere and get approval.

Generally, Class 2 products are somewhere in between. Generally, they require a -- some human testing in a trial, but for sure Class 3 products require, you know, an extensive development program since it's never been done before, and you've really got to prove that safety thing before -- before they're going to let it go

out on the market.
Q. What indication is being sought for the Holaira products?
A. Patients of -- patients with moderate to severe COPD.
Q. Let's turn now, Dr. Wahr, to the use of the name Holaira.
When did -- when did the name Holaira start being used by the company, if you recall?
A. Probably in the first quarter, first quarter of 2013. We -- yeah, plus or minus a month or two, somewhere in there.
Q. And how is the -- how is the Holaira name -- how is the Holaira name used?
A. We use it -- I mean, it's the name of the company. It's on the building. It's -- it's on our business cards. It's the name on our Website, and it's -- and it's the name on -- you know, on the product.
You know, I mean, it's the Holaira Lung Denervation System. It's on the console, and it's -- we use it on our slide template -- our PowerPoint slide template that we use when we present abstracts and

our scientific data. I mean, it's the name of -- it's the name of the system and the name of the company, so it's on that stuff.

Q. At what events, if any, has Holaira presented to physicians?

A. Publicly, public presentations of our company to date has only happened one time, and that was -- our coming-out party for public presentation was at the European Respiratory Society meeting in Munich, Germany last fall.

That's the only public presentation, you know, at a -- at a trade show, and we did not have a booth. It was -- we were start of the scientific agenda. We had abstracts that were accepted for presentation, and we did one evening symposium, you know, where we summarized our product for the -- you know, for the attendees.

Q. And what were the attendees? Who was the audience at that --

A. Primarily interventional pulmonologists, as well as, in general, pulmonologists. That would -- that made up the majority of the

audience, and then there were industry people there as well.

You know, whenever a new product is kind of like shown at one of these meetings, other companies that are in the space always come out of interest as well, as you would expect.

Q. When I asked a few questions ago, you made a distinction, I think, between public and private presentations?

A. Yes.

Q. Has the company done any private presentations?

A. Yes. Oh, yes. I mean, everybody -- you know, all of our physicians, who are investigators in our clinical trials, you know, obviously, have had private presentations, and not only private presentations, but have gone through training, extensive training, on how to use the device, and so, there's been meetings with that group of doctors, but we also have meetings with physicians in private that are other key opinion leaders, KOLs, that stands for key opinion leaders, leading physicians

in the interventional pulmonary space, to get their feedback and input and, you know, reaction to what we're doing.

So there's been a number of those meetings as well.

Q. And in those meetings you use the name Holaira?

A. Yes.

Q. Approximately how many private presentations would you say that Holaira has had?

A. Over -- since I have been CEO, those types of meetings, fairly formal meetings, I would say at least 50.

Q. And are those to interventional pulmonologists in the United States or elsewhere?

A. Both Europe and the United States.

Q. And within the United States, how many of those types of meetings have you had?

A. Probably about a third of them have been with US docs; two-thirds of them with European physicians.

Q. Has --

A. Our US -- our US -- we have no US clinical sites yet. You know, we're hopeful we'll

have some later, you know, in the not too distant future.
Q. Has Holaira used the name Holaira in any press releases?
A. Yes.
Q. Do you know about how many in the last, what is it, three and a half years?
A. Since I have been CEO, there have been five press releases.
Q. What's the general topic of those press releases, if you recall?
A. The majority of the -- most of them were related to finance. It's common to do press releases after you raise money successfully, and -- or to announce, say, a key new employee hire, and then I think one of them was on -- you know, was announcing our clinical data that was going to be shown at the European Respiratory Society.
Q. Has Holaira --
A. They're -- they're all posted on the Website.
Q. Has Holaira clinical data been published in any medical journals?
A. Yes. Yeah, our Phase 1 -- our first

clinical trial now is published in a peer-reviewed journal called Thorax.

Q. Has -- are you aware of any confusion between Holaira and Alair?

A. None.

Q. Are you aware of any confusion between or about Holaira's affiliation or lack of affiliation with Boston Scientific?

A. None.

Q. Let's turn now, Dr. Wahr, to the sales process for the Holaira product.

First, who is the -- the target customer for the Holaira products?

A. The interventional pulmonologists.

Q. Why is that?

A. Because our product will -- will be labeled that it is only for use by an interventional pulmonologist. That will be -- and then even if you are a Board-certified pulmonologist, just that by itself is not sufficient. You will also have to go through and finish the formal training program.

Q. I'll dig into the formal training program in just a minute.

A. Okay.
Q. But you mentioned it will be labeled?
A. Yeah.
Q. What -- what does that mean, "it will be labeled"?
A. Well, the -- the -- when the FDA approves a product, they -- they define in the label who the patients are that -- what are the -- what are the inclusion criteria that the patient must have in order to be a candidate for the therapy.

In our case, it would be moderate to severe COPD, you know, and what the testing parameters are that make that patient formally eligible to get the therapy; and, number two, what are -- what are the requirements for a person to be -- to use the device.

You know, what is the training qualifications, you know, for a person to be able to use the device. Those are defined as part of a product being approved by the FDA.

Q. What -- what sales -- I understand the product isn't commercially available as of

yet, but does the company have some sense as to what sales process it intends to employ when the product becomes commercially available?

A. Yes. I mean, yes. I mean, we don't have a detailed plan, because that's out there in the future, you know, a number of years, but -- but at a high level, yes, and our plan for commercialization will be a direct sales force.

Q. And what do you know by a direct sales force?

A. Meaning --

Q. Can you describe that?

A. Meaning we will not use distributors or other third-parties to -- to sell our product.

Q. And how would the -- what's the concept of how the direct sales force would go about selling the product?

A. It would be -- it would be direct from -- I mean, it would be direct to the interventional pulmonologists. It would be direct point-of-contact with the interventional pulmonologists.

Q. You mentioned that that's a few years out. Do you have an estimate as to how far out that is?
A. The -- the --
Q. I should have asked a more clear question.
[redacted]
Q. You mentioned that training --
A. Yes.
Q. -- will be required to be able to use this product?
A. Yes.
Q. What -- can you describe for me what that training is?
A. Yes, the -- the training program, it isn't just a training program for a commercial product. The training program is also a

requirement even to just be doing our clinical trials at this point in time, you know, where we -- anybody who's going to be an investigator for us has to go through the formalized training program, which consists of both didactic, where it's slide presentations, you know, to instruct them in every aspect of how to use both the console and the device itself, you know, how to run them, how to position them.

But there's also a -- you know, so, there's a mechanical part to it, but there's also an education about patient selection, you know, entry criteria, you know, for patients and also how the patients are followed up afterwards. So, it's a comprehensive, you know, all -- all parts of it.

And in addition to the didactic presentations, there's also a hands-on training process, where -- where they use the device on a mannequin, as well as on a human cadaver, in a cadaver lab.

Q. And who provides this training to physicians?

A. The company. We do, the company. You know, our -- our technical team.
Q. Company employees?
A. Company employees, yeah.
Q. Is there any support provided by company employees at actual patient cases?
A. Yes. After -- after completing the training program, there is company support at all of the clinical cases, 100 percent of them, and when -- and we anticipate that that will go on throughout the entire clinical program, and the term they use for this is proctoring, you know, in the medical world; and there will be a requirement that comes in at the time of approval by the FDA for when the product goes commercial will be a specific designation for how many cases after completing the training program a physician has to be proctored before he can really be turned loose, you know, to just do these cases in an unsupervised fashion.

And where that number is going to be for the number of required proctored cases, isn't settled yet. I mean we'll learn more about that as -- as we go through

the whole clinical program, but I would expect it will probably be in the three-to-five-case range.

Q. How -- how, if at all, are patients targeted for Holaira marketing?

A. We don't do any -- any -- any marketing to patients, you know, at this point. Patients have the potential to become aware of us, you know, by finding -- you know, by discovering it, you know, by reading journals or going on the Website or things like that, but we don't actively do any marketing to patients.

Q. What is the -- does the company have a sense as to what the price-point for the Holaira System will be once it's commercially available?

A. Well, it will be -- there's two components to it. There would be the catheter, you know, the dNerva catheter, will have -- which is a disposable, one-time use, and will have one price; and then the console, which can be used repeatedly, you know, on many cases, will be another.

So, there will be two purchased

things; the console and the catheter. [redacted]

Q. Are you familiar -- in your time as an interventional cardiologist, and as well as based on your experience selling Class 3 medical devices, are you familiar with the process for purchasing Class 3 medical devices?

A. In hospitals?

Q. Correct.

A. Yes.

Q. What -- who makes the decision to purchase a Class 3 medical device?

A. Hospitals have what's called a purchasing department, and the purchasing department is really the one that -- they issue the checks. I mean, that's where -- that's the key thing you got to get past, and they have formalized processes for how they make the decisions.

And, in general, the process starts

when a physician tells the purchasing department that there's a new product, or in some cases, the product's been around, but just hasn't been there on -- you know, available before, a physician makes a request that they would like to have a product, you know, put in the inventory or on the shelf, so to speak, at the hospital.

And then when that happens, a process starts in the purchasing department, where -- where it's basically an application process where you have to educate the purchasing department about what it is, what its merits are, you know, what its potential benefits are, you know, to the patient.

It's usually initiated by -- it can be initiated by any one of the physician, you know, specialties in the hospital. Generally purchasing departments then consider other things. They might -- they might ask for feedback from other specialties that would know about this. They -- they would -- they may look for medical society recommendations. They would -- they also would look very carefully

about whether there's reimbursement available.

Sometimes hospitals will decide this is a great product, but because no reimbursement is available from the insurance companies, they still won't put it on the shelf. You know -- you know, and that's when it sometimes comes into conflict, you know, hospital -- I mean, physicians versus hospitals that -- you know, if the physicians want it, and the hospital doesn't want to buy it, those are interesting discussions, but it's a pretty involved process.

Q. And why does the direct sales force -- or why is the intent for the direct sales force at Holaira to work directly with interventional pulmonologists as opposed to the purchasing department?

A. It's both a combination of the complexity of the product, plus the cost, and -- and that's too much to really rely on a distributor for.

You know, distributors are really -- in my experience, do best with

commodity-type products, you know, that don't require education. You know, like for example, if you had a -- there's 30 different hip prostheses out on the market, and they're very -- and in many cases very hard to differentiate one from another. You know, a company might give a distributor, here's our hip prostheses, go out there and sell it, and -- because it's not a technical sale, and if -- but as products get more and more sophisticated, it's a -- you need your own highly, highly educated company representative to go in there and -- and educate -- you know, educate that physician, and then the hospital too.

I mean, you know, the company reps get involved in the -- in the education part even working with the purchasing departments as well.

Q. And what -- what role does the physician have in the decision to purchase the product?

A. He is a -- he makes a recommendation, but his recommendation is essential to starting the process. I don't know of any situation

where a hospital purchasing department would just, on their own, decide they want to put something on the shelf. That wouldn't happen.

Q. With a Class 3 medical device, is it possible for a patient to purchase the product?

A. No.

Q. Why not?

A. It can't be sold. It's not for sale to -- to patients. It's for sale only to -- to the hospital's purchasing department on the recommendation, you know, of the pulmonologist.

Q. How would a patient who comes across the Holaira name, once the product's commercially available, how would that patient possibly get the treatment?

A. They would have to -- they would have to identify a hospital and physician that -- that are approved to do the procedure and go to that medical center.

MR. HANSEN: Why don't we go off the record. I'll go through my notes and see if I have any other questions for you,

Dr. Wahr.

THE WITNESS: Okay.

(Break taken.)

MR. HANSEN: Dr. Wahr, I have no further questions for you at this time. Thank you.

Do you want to take a break, or do you want to --

MR. WALZ: Yeah, if we can take a break, and I can just kind of get some docs ready, and then we'll come back.

(Break taken.)

EXAMINATION

BY MR. WALZ:

Q. Dr. Wahr, are you ready?

A. Yes.

Q. Okay.

MR. WALZ: I'll just have you mark this first.

(Exhibit Number 3 was marked.)

BY MR. WALZ:

Q. So, Dr. Wahr, you've been handed what's been marked as Deposition Exhibit Number 3. This was a document produced by Holaira.

Do you recognize that document?

A. Yes.
Q. And if we turn to page -- well, it's Bate-numbered 1392?
A. Yes.
Q. At the bottom there, there's -- next to signature, Dennis W. Wahr; is that correct?
A. Yes.
Q. And that is your signature?
A. Yes.
Q. And --
A. Well, I don't see a signature, but it's my name typed.
Q. That's an electronic signature, correct?
A. Oh, okay. All right.
Q. And you signed this application, correct?
A. I -- I probably did, yes. It's three years ago.
Q. So, it's possible that someone else signed this application?
A. No, I just don't see my signature on here.
MR. HANSEN: Objection to the form.
THE WITNESS: No. Yeah, so, you know, I mean I'm taking your word for it that somebody printed this up with numbers.
BY MR. WALZ:

Q. Right. And you reviewed this application before you signed it, correct?
A. Yes.
Q. And you understood what you were applying for when you sign the application, correct?
A. Yes.
Q. And all the information in this application was correct as of December 19th, 2012 when the application was signed, correct?
A. I haven't -- it's been a long time since I've read it, but I assume it was.
Q. So, if we look at the -- let's see here, if we look at the page Bate-numbered 1391?
A. Yes.
Q. You will see, next to International Class 10, there's a description that reads: Medical devices, medical apparatus and instruments?
A. Yes.
Q. Now, that identification was at some point amended; is that correct?
A. I don't know if we amended this or not. I don't know the answer to that.
Q. Okay.
A. I don't understand your question.

(Exhibit Number 4 was marked.)

BY MR. WALZ:

Q. So, you've been handed what's been marked as Deposition Exhibit Number 4. This is a printout from the United States Patent and Trademark Office test database, and next to the Goods and Services heading, there's a description that reads: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases.

Do you see that?

A. Yes.

Q. And that's different from the description we saw on Exhibit 3, correct?

A. In that paragraph that starts, "International Class;" you're referring to?

Q. Correct, on Exhibit Number 3.

A. Well, it's -- I mean, the wording is slightly different, but it's saying the same thing. I mean, it's -- it's a device for treating obstructive -- it's a medical apparatus and instrument. The one -- the one on the right is -- looks like it's more detailed.

Q. And when you say "the right," you're referring to Exhibit Number 4, correct?
A. Right.
Q. And looking at Exhibit Number 4, does that description accurately reflect the device that will be used in connection with the Holaira mark?
A. Yes, this is appropriate.
Q. Okay. And you have no intention of further amending or clarifying the identification description that you see in Exhibit Number 4, correct?
A. Not at this point in time.
Q. Okay. And just for a purpose of clarity, I think when you were discussing before the difference between dNerva -- the mark dNerva --
A. Yes.
Q. -- and the Holaira mark, you mentioned that dNerva will be used as the product name, but that Holaira is going to be the company name?
A. Holaira -- Holaira is the company name. The system, you know, the whole system that consists of the console, you know, and the

catheter, we call the Holaira Lung Denervation System.

Q. Okay.

A. But the catheter, the catheter that's disposable, the part that goes through the bronchoscope, is the dNerva catheter.

Q. I see, okay.

(Exhibit number 5 was marked.)

BY MR. WALZ:

Q. So, you have been handed what's been marked as Deposition Exhibit Number 5.

Do you recognize this document?

A. Yes.

MR. HANSEN: I'll just object it's outside the scope of the direct examination.

MR. WALZ: We'll bring it within the scope.

THE WITNESS: Yes.

BY MR. WALZ:

Q. You do recognize it? Okay.

And if we flip to the second to the last page again at the bottom, we see next to signature, Dennis Wahr?

A. Yes.

Q. That is your signature?

A. Yes.
Q. And you did sign this application as well?
A. Yes.
Q. Okay. And then if we look on the third page from the end, next to Class 10, we see medical devices, medical apparatus and instruments, correct?
A. Yes.
(Exhibit Number 6 was marked.)
BY MR. WALZ:
Q. So, you have been handed what's been marked as Deposition Exhibit Number 6. This is a printout from the United States Patent and Trademark Office test database. It's for the dNerva mark, and, again, next to the heading Goods and Services, we see medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases?
A. Yes.
MR. HANSEN: Objection, outside of the scope of the direct examination.
BY MR. WALZ:
Q. And similar to the Holaira mark we saw before, comparing the Exhibit 6 to

Exhibit 5, the description was amended, correct, to what appears on Exhibit 6?

MR. HANSEN: Same objection.

You can answer.

THE WITNESS: Okay. The words on the -- on the Exhibit 6 are -- are slightly different than here, but, again, it appears like they're saying the same thing.

BY MR. WALZ:

Q. And if we compare Exhibit 6 with, I believe -- what was the Holaira -- I can't remember the number -- test page? So, is that Exhibit 4?

A. 4.

Q. So, if we compare what's in Exhibit -- the identification in Exhibit 6 with the identification of the goods description in Exhibit 4, those descriptions are the same?

A. They look the same.

MR. HANSEN: Same objection.

BY MR. WALZ:

Q. Okay. And if you look at Exhibit 1 --

MR. HANSEN: Do you mean Exhibit 3, Brad?

MR. WALZ: I'm sorry, Exhibit 3.

BY MR. WALZ:

Q. If we look at the page that's numbered 1391, underneath that International Class 10, there's an Intent to Use, and it says: The applicant has a bona fide intention to use the -- or use through an applicant's related company or licensee the mark in commerce or in connection with the identified -- on or in connection with the identified goods or services.

Do you see that?

A. Yes.

Q. And at the time you signed this application, you had the present intent to use the Holaira mark in connection with a medical device for treating obstructive lung diseases, medical apparatus and instruments for treating obstructive lung diseases, correct?

A. Yes, after going through all the appropriate regulatory approvals.

Q. Right.

A. Yeah.

Q. And after -- if we look at Exhibit 5, that's the dNerva application, looking on page --

page 4, under that International Class 10, we have that same "intent to use" language?

MR. HANSEN: Object, outside the scope.

You can answer.

THE WITNESS: Yes.

BY MR. WALZ:

Q. And the dNerva application was filed, if we look at the second to the last page -- or was signed, I should say, on April 25th, 2013, correct?

A. Yes.

Q. And then if we look at Exhibit 6, and we look at the filing date, it was actually filed the same day as well, correct?

A. Yes.

Q. And that's approximately four months after the Holaira application, which is Exhibit 3, was signed by you, correct?

A. Yes.

Q. So, my question is: How could you have a bona fide intent to use the Holaira mark if four months later you filed an application for the dNerva mark with the exact identification of goods descriptions?

A. Well, the -- we decided that we wanted a distinct name for -- for the actual catheter itself versus the system, and so, we wanted one more -- we wanted a different -- it's different parts of -- it's a specific part of the bigger system.

You know, the system is the Holaira Lung Denervation System, but the disposable product is its own entity. It's different.

Q. So, is the dNerva application, the ID in that dNerva application, misdescriptive of the goods that will actually be used in connection with the mark?

MR. HANSEN: Object to form and outside the scope.

BY MR. WALZ:

Q. I guess I'm trying to find out if one of these applications is misdescriptive of -- of what you intend to use the mark for?

A. Well, the -- the description is general. I mean, they both apply. I mean, it's accurate for both. It's a correct designation for both -- both marks.

Q. But you said dNerva would be used in connection with the disposable catheter, not

a medical device for treating obstructive lung diseases?

A. Well --

MR. HANSEN: Object to the form.

THE WITNESS: Well, the catheter is part of the system. So, it would be used in the same way, and you're confusing me. I'm not sure where you're going with that.

BY MR. WALZ:

Q. That's okay. We can move on.

A. Okay.

Q. So, the Holaira device can be used to treat chronic asthma, correct?

A. In theory, if we -- if we chose to go that way, in theory, it could, yes. It would be a completely new clinical development program.

Q. And that is an area that you're thinking of expanding into, correct?

A. Not right now.

Q. But it is something that you have --

A. It's theoretically possible that we could make that decision at some point in the future.

Q. Right. But you've promoted that to

potential investors and -- and identified it as a potential area?

A. Yes.

Q. And you market -- as you testified, you market the device to physicians, right, interventional pulmonologists?

A. Interventional pulmonologists.

Q. Okay. And you're marketing that as a treatment for COPD, correct?

A. Correct.

Q. And that term is understood as an umbrella term, right?

A. COPD, yes.

Q. And so, under that umbrella, would include a condition such as chronic asthma, correct?

A. No. COPD is generally -- is generally felt to have two major components. One would be emphysema, and the other would be chronic bronchitis.

Asthma is a -- is felt to be a distinct different disease process. We -- we do not believe that -- we certainly believe that asthma does not fall under our label indications.

MR. WALZ: Okay. Would you mark

that as 7, I believe.

(Exhibit Number 7 was marked.)

BY MR. WALZ:

Q. So, you've been handed what's been marked as Deposition Exhibit Number 7. It is a printout from the medical-dictionary.thefreedictionary.com. These are definitions concerning COPD.

If you turn to page 5, and I guess it flows over into page 6, and if you look at page 6 first, this is -- well, the definition that begins on page 5 for COPD that turns over -- or spills over onto page 6 at the bottom, this is a definition from McGraw-Hill Concise Dictionary of Modern Medicine.

Do you see that at the bottom?

A. Yes.

MR. HANSEN: I'll object to the document as containing hearsay.

BY MR. WALZ:

Q. So, if you turn to the first page -- or on page 5, that final dictionary definition for COPD states: Chronic Obstructive Pulmonary Disease, Pulmonology, an umbrella term for a

group of usually progressive lung disorders with overlapping signs and symptoms, including asthma.

Do you see that?

MR. HANSEN: Object, hearsay, foundation.

THE WITNESS: I'm not sure what page -- I can't seem to find the page you're on.

BY MR. WALZ:

Q. So, at the top of each page, there are page numbers; do you see that?

A. Oh, okay. What page?

Q. Page 5, and that definition begins at the bottom and spills over.

So, I was saying, do you see on page 5, that last definition of COPD?

A. Yes.

MR. HANSEN: Same objections.

BY MR. WALZ:

Q. And it says: Chronic Obstructive Pulmonary Disease, Pulmonology, an umbrella term for a group of usually progressive lung disorders with overlapping signs and symptoms, including asthma?

MR. HANSEN: Same objection.
BY MR. WALZ:
Q. Do you see that?
A. Yes.
Q. Okay. And then if we turn to page 6, we see another definition of COPD at the bottom. This is from the Gale Encyclopedia of Medicine, and it says: A term used to describe chronic lung diseases, like chronic bronchitis, emphysema and asthma?
MR. HANSEN: Same objections.
BY MR. WALZ:
Q. Do you see that?
A. Yes.
Q. Do you have any reason to dispute these definitions?
A. I think that our -- our definition of Chronic Obstructive Pulmonary Disease is what we -- our indications on our labelling indication are for chronic bronchitis and emphysema. Asthma is excluded. We don't treat asthma.
Q. Okay. But a doctor would understand, or a physician would understand, the term "COPD" according to these medical dictionary

definitions to include asthma?

MR. HANSEN: Objection, form, foundation and hearsay.

THE WITNESS: No, I don't agree.

BY MR. WALZ:

Q. But the Holaira System will compete with the Alair System; is that correct?

A. No, it will not.

Q. You said though that the Holaira System could possibly treat asthma?

A. We have no clinical development program for asthma, and every pulmonologist, as well as interventional pulmonologist, sees them as distinctly different diseases, and the only way we could treat asthma would be if we started over from scratch with a completely new Phase 1, you know, feasibility study in asthma patients, which, at this point, there has been nothing initiated to start such a program. It would be unaffordable for us to do that.

Q. To start --

A. An asthma program.

Q. -- an asthma program?

A. Yes.

Q. But you are marketing that to your investors as a potential area of growth, correct?
A. If -- in the future, if a new -- if a new -- if another company were to buy Holaira, they could make a decision to start an asthma program in theory, but understand that it would be going all the way back to the starting point and starting at point 0 in terms of that, and -- and the earliest commercialization date for us to have a label indication for asthma, if somebody wanted to start that today, might be 2025.

I mean, it's way out there, and it would be another $100 million development program, which has not started at this point.

(Exhibit Number 8 was marked.)

BY MR. WALZ:

Q. Showing you what's been marked as Deposition Exhibit Number 8.

Do you recognize this document?

A. Yes, yes.
Q. And what is this?
A. This is a presentation that I gave at the Piper Jaffray Healthcare Conference.

Q. So, if you turn to page 2, in the heading, it says: Holaira, Treatment For COPD and Asthma, right?
A. Yes, yes.
Q. Okay. And if we look at page 11, it's Bate-numbered 12 --
A. Yes.
Q. -- we see a -- a chart of revenue projections, and then at the bottom of that chart, there's a box?
A. Yes.
Q. And it says: COPD and asthma indication split 70/30 in 2022?
A. Yes.
Q. And then if we turn to page 12, Bates-numbered 13, and again we see at the top in the heading, this is a competitive landscape, and in the chart, there is, in the second box below company product, Holaira, and then if we go to the right under COPD, there's a checkmark; under asthma, there's a checkmark; and under emphysema, there's a checkmark.

Do those checkmarks indicate that the Holaira device can be used --

A. Yes.
Q. -- to treat these conditions?
A. Yes, it could, yes.
Q. And then if we move below the Holaira box, there's an entry for BSC that says, formerly Asthmatx/Alair; and under that, we see a checkmark in asthma?
A. Yes.
Q. And that indicates that the Alair System is used to treat asthma, correct?
A. Yes.
Q. And Boston Scientific is identified on a chart where you've labeled it competitive landscape as a competitor, correct?
A. Yes.
Q. And if we turn to the very last page -- I'm sorry, page 17, Bates-labelled 18, we see a slide labeled -- titled: Series D Financing Highlights -- I'm sorry, are you there?
A. Yeah, I know it. Go ahead.
Q. And underneath the bullet point, Milestones Through 2016, there's a subpoint for asthma as part of the clinical heading?
A. Yes.
Q. And that there's six months of data from the

asthma feasibility study.

Does this mean that you've already started a feasibility study for the use -- use of the Holaira device to treat asthma?

A. No, this was -- this was a slide done, because at the time we were raising our $40 million, we did not have an asthma program. We wanted to leave open the possibility that if one of our investors -- if our lead investor wanted us to start one, that's when this could be available, but, in fact, when we closed the $40 million financing, our new investors did not want to do an asthma program.

So, therefore, this has completely dropped off the radar screen, if that makes sense to you.

Q. Yep.

A. So, our clinical program is emphysema and chronic bronchitis.

Q. Let's talk a little bit about targeted lung denervation.

So, I think, as you testified before, targeted lung denervation, TLD, is the generic name that you have created for

your procedure, correct?
A. Yes.
Q. And that's similar to what, you know, Boston Scientific had done with bronchial thermoplasty?
A. Exactly.
Q. And TLD is a procedure that will require a patient's informed consent, right?
A. Yes.
Q. And with respect to the informed consent obligations, one of the things that will have to be discussed is the nature of the procedure, correct?
A. Yes.
Q. So, as you described before, the use of a bronchoscope, the use of a catheter to place a energy emitter within the main bronchi, and then the administration of energy in that main bronchi, correct?
A. Correct.
Q. And there will have to be a discussion with the patient that the Holaira device will be used as part of that TLD treatment?
A. Absolutely.
Q. And in discussing the nature of the

procedure, you'll also have to explain to the patient -- or the doctor will, I should say, that, as you described, the treatment is intended to denervate the nerves, that it will not have -- it's not intended to avoid any of the smooth muscle of the bronchi, correct?

A. Yes.

Q. And, in fact, there is no effect to the smooth muscle through targeted lung denervation, correct?

A. That -- that's what we believe, yeah.

Q. So, then you will have to discuss the risk and benefits with -- or the physician will, with respect to TLD, and you'll also have to discuss any alternatives, correct?

A. Yes, yes.

Q. And an alternative would be bronchial thermoplasty?

A. For what we do? No, bronchial thermoplasty is not indicated for COPD -- I mean, for chronic bronchitis or emphysema.

Q. But that -- so, bronchial thermoplasty, though, has an effect on the smooth muscle tissue?

A. Yes.
Q. And --
A. That's what they say, yes.
Q. And we talked about how COPD is an umbrella term, and that chronic asthma is underneath that umbrella?
A. You -- you've completely manufactured that. No interventional pulmonologist buckets asthma with emphysema or chronic bronchitis. Those are -- the two things that we treat are completely different from asthma period. That's why we have them in the three columns. Boston cannot -- is not an label to treat chronic bronchitis or emphysema.
Q. But there are variations to asthma, isn't there? You can have acute asthma?
A. There -- there is a classification of asthma, where -- where, in the severest form, some of the pulmonologists will say that it starts to look like COPD, but -- but those are not -- those patients are not included in our protocol or will be on-label.
Q. So, a patient --
A. They're different.

Q. But a patient with chronic asthma, though, if they were to talk to a physician about TLD, a physician would have to have a discussion at least about what treatment is available for asthma, correct?
A. No, because there's --
MR. HANSEN: Object to form.
THE WITNESS: -- there's no label indication for what we do.
BY MR. WALZ:
Q. Is there ever any operable use?
A. Huh?
Q. Does operable use happen at all?
A. It never -- it never happens with a non-commercially-approved product. [redacted]
Q. Oh, right, obviously. We're not -- yeah, right, I guess, yeah, to bring --
A. I mean, if they want to go to jail, they can do that if they want.
Q. Yeah, we're talking about a product that is not yet commercialized, right?
A. Right.
Q. We're talking about an intent to use

trademark application.

So, just so I understand, as part of a -- of a doctor's informed consent obligation, you're saying that a patient that they're advising with respect -- that has chronic asthma would not have to be told that, in addition to targeted lung denervation, which could be used to treat their condition, there's a separate procedure called bronchial thermoplasty, which could be an alternative to targeted lung denervation?

MR. HANSEN: Object to the form, lack of foundation.

THE WITNESS: Absolutely not. You're really mixed up on this. You know, the -- an asthma patient under any circumstances, no doctor in the world would tell an asthma -- would tell an asthma patient that TLD is an alternative therapy for what they have.

TLD at this point is an experimental therapy only being tested in chronic bronchitis and emphysema that, [redacted] they will get an approval, and

there's nothing even in the works.

They would have absolutely no obligation to tell a patient that.

BY MR. WALZ:

Q. Okay.

A. And even if they did, it would be totally unavailable.

Q. Okay. So, what -- yeah, I guess, again, we're talking -- again, you're not using the mark -- the device -- so, I'm not talking about -- we need to think about in terms of when your product is actually available and gets approval, [redacted]

A. Right.

Q. So, when you're both in the market --

A. [redacted]

Q. [redacted] So, the two treatments are now actually available.

TLD is available to persons?

A. For asthma -- I mean, excuse me, TLD for chronic bronchitis and emphysema, right?

Q. COPD, right?

A. No.

Q. That's --

A. No, if you are choosing to arbitrarily use

COPD as this higher bucket, like your thing says, then -- then it's an inappropriate umbrella, because we are only going to be approved for emphysema and chronic bronchitis.

(Exhibit Number 9 was marked.)

BY MR. WALZ:

Q. Handing you what's been marked as Deposition Exhibit 9.

If you turn to the second page?

A. Yep.

Q. This is -- it's titled: Six Degrees Confidential Backgrounder.

Do you recognize this document?

A. What's the date of this one? October 12. Yeah, this one would have been created about a week after I started, but I recognize a lot of the things in here. I'm not sure I've seen this before, but go ahead.

Q. Okay. So, if we look at just even the executive summary, and this was -- let me back up.

I mean, the intent of this document was to educate Six Degrees, who was your marketing firm that was retained to help you

with the naming process, right --
A. Yes.
Q. -- to understand your company?
A. Yes.
Q. Okay. So, in the executive summary, there, it says that: IPS is a system -- the main objective of the IPS System is the development of a commercial product to enable a new therapeutic procedure, TLD, which will improve respiratory function for moderate to severe COPD patients?
A. Yes.
Q. And it doesn't say chronic bronchitis or emphysema, correct?
A. You know --
MR. HANSEN: Feel free to review the entire document before you answer questions about it.
THE WITNESS: Yeah, I think you're taking this out of context. Our COPD definition that we use throughout the entire company is COPD is chronic bronchitis and emphysema. It is not asthma. Our clinical programs, you know, make it clear that asthma is not included.

But, by the way, could our device eventually at some point be used to treat asthma? The answer is yes, and I've said that already, but we're not developing it for that. So, that's the answer to your question.

You know, so --

BY MR. WALZ:

Q. Okay.

A. -- I mean, you're arguing over the semantics of this, but I can promise you, in interventional pulmonology, we can bring in 20 experts, and they all see asthma, chronic bronchitis and emphysema as three completely different entities.

Now, most people traditionally would put just two of them under COPD, chronic bronchitis and -- chronic bronchitis and emphysema under COPD. That's what you see under every commercial on TV when you see Spiriva advertised. And they put asthma over here in a different category, because its mechanism of action is different, and it's a different disease process.

Q. Right.

A. And -- and that's -- that's how we use it, but the point is is that I'm not denying the fact that, if we ever -- if a future owner or investor or something wanted to start an asthma program, our device could -- could do that, and that's why it appears in there. I'm just simply saying we're not doing that right now.

Q. Right.

A. And -- and if somebody decided to do it, it would be way out there.

Q. Okay.

A. And I don't understand what that has to do with the trademark anyway.

Q. Yeah, this is just -- this is just -- you know, in all of the documents I've seen produced by Holaira --

A. Yeah.

Q. -- reference is always made to COPD. So, that's why I just wanted to get some clarification as, you know -- and you even describe it on your Website as an umbrella term?

A. Over --

Q. So --

A. -- over CO -- over emphysema and chronic bronchitis, yes.
Q. But as we saw in some of those medical definitions, you know, asthma has been included as -- under the umbrella?
A. I will go on the record though as the vast majority of people in this space of the experts separate asthma under a completely separate umbrella and not under the COPD umbrella. That's my statement, but it doesn't matter to this anyways.
Q. That's your opinion, right?
A. Right, it's my opinion, and it's clearly the -- the opinion of the vast majority of people that this is how they would classify it.

(Exhibit Number 11 was marked.)

BY MR. WALZ:

Q. So, you have been handed what's been marked as Exhibit 11. This is an email from Mark Laverman to Lorraine and also yourself. You are identified as a recipient, and this email attached two PowerPoint presentations.

One is the messaging blueprint, and the second is the -- the naming -- what is

it called? Is it the naming concept?

So, you previously testified that you were targeting only interventional pulmonologists with respect to your sales efforts?

A. It was the primary target.

Q. So, it's not the only target?

A. It's not the only target.

Q. Okay. What are some of the other targets?

A. Well, if you're putting -- if you wear my hat as the CEO, my primary targets are, number one, the customer, which is interventional pulmonologists. Number two, you're -- you're also targeting with what you do the investors. That's critical for a company at our stage.

You know, those would be -- you know, those would be the two most important, so --

Q. Anyone else?

A. Well, I mean, you're also -- I mean, you're also -- you're also going to target general pulmonologists. You're going to target all of the physicians, you want to have an awareness of that, and you want to target

future acquirers, you know, of the company, you know, so, you know, you want to put out to -- you want to reach out to all of them, and you're happy to have patients gain awareness of it as well.

Q. So, you won't reach out to patients?

A. Not directly, no.

Q. Okay. If you turn to the page Bate-numbered 538, there's a title there of the report called Audience -- Audiences?

A. Which page?

Q. It's Bate-numbered 538.

A. I don't seem to have numbers on mine.

Q. It's on the right -- lower right. Yeah, you got it right there.

A. Oh, here we go.

Q. Yep. So, it's titled, Audiences; you see that at the top?

A. Um-hmm.

Q. And at the far right -- actually, let's back up.

On the left, we have the medical community, which you talked about, right, the interventional pulmonologists, et cetera; the financial community is to the

right of that medical community box; and then at the far right, we have consumers?

A. Yes.

Q. So, you're -- you're telling me you're not going to target consumers?

A. Our -- our marketing -- our marketing efforts right now are clearly related to the interventional pulmonologists. I mean, we certainly don't want to hide this from the patients. We do no active marketing to patients, but eventually down the line -- down the line, if you have a novel medical therapy, you wouldn't -- I mean, you're not going to block that from happening, but you're not going to spend money on it.

Q. You will not spend money on even down the road on --

A. On actively reaching out to the patients. I mean, this will be something with -- I mean, patients with COPD and emphysema come to their pulmonologist, and then -- and they -- it's that pulmonologist then that will be the key decision-maker, the interventional pulmonologist.

Q. So, will you make any -- once you're

commercialized, will you make any marketing material that potentially could be distributed to a consumer?

A. We have no plans at this point. Would we do the stuff like what the pharmaceutical companies do with direct TV marketing, I actually don't believe in that.

Q. But you'll -- so, it's not in your plan to create any marketing material, but is it a possibility?

A. Maybe for some big company in the future. They might choose to do it. It would be a highly ineffective way to do it I think, but --

Q. To market the Holaira?

A. To go direct to patients with a product that only a highly sophisticated subspecialist -- I don't really see St. Jude and Medtronic going to customers to market their particular type of aortic valve prostheses, you know, when they -- when the patient would have no idea what the right prostheses is for the aortic valve. It is possible? Sure. It's not the primary target.

Q. But the Holaira device is tied closely to

TLD, correct?

MR. HANSEN: I'm just going to lodge an objection. You're -- sometimes you pronounce it Holaira, and sometimes you pronounce it Olaira [ph]. I just want to make sure that you're meaning Dr. Wahr's company.

MR. WALZ: Well, as you know, I mean, there's no right way to pronounce a coined term. So --

MR. HANSEN: But I think the issue is you're switching back and forth. I just want to make sure that --

MR. WALZ: Yeah, Olaira, Holaira, I mean, that's referring to -- yeah.

MR. HANSEN: Okay.

BY MR. WALZ:

Q. So, let's look at Exhibit Number 2, and if we turn to the page Bate-numbered 111?

A. Got it.

Q. So, it's true that, at all times during this naming and branding process, that your company, you were aware of Boston Scientific's Alair System, correct?

A. Yes.

Q. And this page that we're looking at, 111, is the list of short names, as you testified to, and you've also testified that you needed to get creative people involved, you needed to select a name -- a new name that was completely unique, correct?
A. Yes.
Q. Unlike any other, correct?
A. That was the goal.
Q. Yet the Holaira mark that you ultimately, you know, settled on has the L-A-I-R string included in it, correct?
MR. HANSEN: Form.
THE WITNESS: Yes.
BY MR. WALZ:
Q. And that is the same string of letters that's in the Boston Scientific Alair mark, correct?
A. Yes.
Q. And you also testified that, based on attending meetings, that you were aware of a lot of "air" marks, although when you referenced the piece of paper that you took out of your pocket, there were only four names on there, correct?

A. Four names on there, yep.
Q. And Xolair, you mentioned, was a drug?
A. Yes.
Q. Singulair is a pharmaceutical?
A. Yes.
Q. VitalAire is a pharmaceutical?
A. Yes.
Q. And Alere, L-A -- A-L-E-R-E, is that a pharmaceutical as well?
A. Yes.
Q. Do you know how prevalent the use is of the Xolair mark?
A. It's -- I don't. I don't know what their market share is, no, but it's displayed prominently at -- you know, on trade booths, you know, at pulmonary meetings, so I assume it's being used commercially quite a bit.
Q. Does the Holaira device compete with Xolair?
A. No.
Q. Does it compete with Singulair?
A. No.
Q. Does it compete with VitalAire?
A. No.
Q. And how about Alere?
A. No. It doesn't compete with bronchial

thermoplasty either.
Q. I didn't ask you that question, sir.
You also mentioned that you had received from consumer feedback about the Holaira mark in -- in connection with the prefix "Ho," that you -- you had received some -- some negative --
A. No.
Q. -- potential negative feedback?
A. No, we didn't -- that was an internal concern when we just were talking about it, you know, but no consumer feedback.
Q. So, you did no external testing or --
A. No.
Q. -- surveys or anything?
A. That was just our internal discussion.
Q. And when you testified that there had not been any confusion, you had also testified that you're not using the mark yet in the United States, correct?
MR. HANSEN: Object to form, foundation, misstates prior testimony.
MR. WALZ: You had asked him if he had ever experienced -- or Holaira had experienced any actual confusion, and he

said no.

MR. HANSEN: Yeah, and you added to the question, and you said that, "you haven't been using the mark in the United States." I think he said it's on their business cards, it's on their Website, it's on their letterhead.

MR. WALZ: I take that back.

MR. HANSEN: I think you misstated prior testimony.

BY MR. WALZ:

Q. Okay. So, you haven't used the Holaira mark in connection with the system, the medical device that you applied for, correct?

A. Applied for -- for to who? So, in the United States, it's on our Website. We show our business cards to US docs, you know, and we -- and, you know, we aren't treating any patients in the US, but, you know, US docs clearly know about -- know about Holaira.

Q. It's on the device yet, correct?

A. Oh, you mean on a device that we use in a clinical setting?

Q. Right.

A. But we -- well, first of all, we're not --

no, we haven't used the device in the US.
Q. Right.
A. But it's not on there anyway, but we haven't used one even if it was.
Q. "Holaira" doesn't appear on the device?
A. I mean, not on our commercial device, no. I mean, it's projected to be on our -- on our device, you know, when we go commercial, but right now we're just using a clinical prototype.
Q. Yeah, I guess, just to clarify, when I'm asking questions about sort of the use of the Holaira mark, we both understand that it's -- you're not commercialized yet, but you're still in clinical.

So, when I'm talking about or asking these questions, I'm asking -- I'm referring to --

A. We anticipate to put "Holaira" -- the word "Holaira" on the console.
Q. Right.
A. But it will say "dNerva" on the catheter.
Q. Okay.

MR. WALZ: Can we just take five minutes, and I'll see if I've got anything

else, and we can wrap-up.

MR. HANSEN: Sounds like a plan.

MR. WALZ: Go enjoy our 4th of July.

(Break taken.)

MR. WALZ: I've got no further questions for you, Dr. Wahr.

MR. HANSEN: And I have no further questions for you either, Dr. Wahr.

We'll read and sign. Thank you.

(At 11:40 a.m., the deposition was recessed.)

ERRATA SHEET

Page/Ln	Correction	Reason

I, DR. DENNIS WAHR, have read this deposition transcript pages 1 - 112 and acknowledge herein its accuracy except as noted on the errata sheet.

_____
Signature

_____
Notary Public

STATE OF MINNESOTA

CERTIFICATE

COUNTY OF WASHINGTON

I, Alexis Jensen, hereby certify that I reported the deposition of Dr. Dennis Wahr on the 2nd day of July, 2015 in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the truth and nothing but the truth concerning the matter in controversy aforesaid;

That I was then and there a notary public in and for the County of Washington, State of Minnesota; that by virtue thereof I was duly authorized to administer an oath;

That the foregoing transcript is a true and correct transcript of my stenographic notes in said matter, transcribed under my direction and control;

That the cost of the original has been charged to the party who noticed the deposition and that all parties who ordered copies have been charged at the same rate for such copies;

That the reading and signing of the deposition was not waived;

That I am not related to any of the parties hereto, nor interested in the outcome of the action and have no contract with any parties, attorneys or persons with an interest in the action that has a substantial tendency to affect my impartiality;

WITNESS MY HAND AND SEAL this 10th day of July, 2015.

_____

Alexis Jensen
Notary Public

Errata Sheet for the Deposition of: **Dr. Dennis Wahr,** taken on 07/2/2015
Case Name: ***Boston Scientific and Ashmatx, Inc. v. Holaira, Inc.***

PAGE	LINE	FROM	TO	REASON FOR CHANGE
10	11	start	stop	Transcription Error
10	20	insert "it is my belief" before the word "all"		Correction
13	21	Interventional	Innovative	Misstatement
19	12	and	within	Correction
44	16	Alero	Alere	Transcription Error
44	20	Alero	Alere	Transcription Error
45	1	A-L-E-R-O	A-L-E-R-E	Misstatement
51	15-16	Delete "to understand your--your efficacy of a mark"	of your efficacy	Correction
54	15	Start	part	Transcription Error
92	5-6	it's not intended to avoid any of	it is intended to avoid the smooth	Transcription Error
93	13	an	on	Transcription Error
94	11	operable	off-label	Transcription Error
94	13	operable	off-label	Transcription Error

Witness Signature ***Dennis Wahr***

7/28/15
Date

Notary Public

AMY LYNN WOLTER
NOTARY PUBLIC
MINNESOTA
My Commission Expires January 31, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

- -

Boston Scientific Corporation and
Asthmatx, Inc.,
Opposers, Opposition No. 91215699
and
Holaira, Inc.,
Applicant.

- -

- -

DEPOSITION OF
DR. DENNIS WAHR

- -

Taken July 2nd th, 2015 By Alexis Jensen

APPEARANCES:

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I N D E X

INDEX OF EXHIBITS

NUMBER DESCRIPTION

PREVIOUSLY-MARKED EXHIBITS REFERRED TO:
(NONE)

THE DEPOSITION OF DR. DENNIS WAHR, is taken on this 2nd day of July, 2015, at Oppenheimer, Wolff & Donnelly, LLP, Campbell Mithun Tower, Suite 2000, Minneapolis, Minnesota, commencing at 9:07 a.m.

DR. DENNIS WAHR,

having been called as a witness, being duly sworn, testified as follows:

EXAMINATION

BY MR. HANSEN:

Q. Good morning, Dr. Wahr. I'd like to start out today by just having a little bit of a discussion about your background, okay?

A. Okay.

Q. Let's start with your education, starting with college, and if you would, take me through to your highest professional degree or certification.

A. Okay. I went -- I went undergrad college to a small liberal arts school in Michigan called Albion College, A-L-B-I-O-N. Then I went to medical school at Wayne State University in Detroit, and then did my internal medicine residency, three years, at

the University of Michigan. Then I did my cardiology fellowship at the University of California, San Francisco, went to UCSF, three years there, where I became an interventional cardiologist.

I spent one year on faculty there at UCSF. Then I went back to Michigan, where I practiced cardiology for about 12 years at -- you know, in Ann Arbor, where I was in private practice at St. Joseph Mercy Hospital and was a clinical professor of cardiology at the University of Michigan.

Then I took a leave of absence for one year to come to Minneapolis and -- and become a medical device entrepreneur. I started my own medical device company, and that was in the year 2001, and since -- and never went back. I never went back and practiced -- I took a one-year sabbatical and never went back.

Q. When?

A. And have been here ever since, for the last 15 years.

Q. Were you a Board-certified interventional cardiologist?

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A. Yes, yes, I was what they called triple Board-certified. You know, I was Board-certified in internal medicine. I was Board-certified in cardiology and Board-certified in interventional cardiology; all three different levels of Board certification.

Q. Okay. What's the -- what's the difference between cardiology and interventional cardiology?

A. Cardiologists do -- there's probably four big divisions of cardiology. There's interventional cardiology; there's electrophysiology; there's diagnostic cardiology, which would be things like echocardiographies and MRI scans, you know, they're almost like radiologists; and then there's intensive care cardiology, you know, working in ICUs and things like that.

And they all have their separate Boards, so, you know, it just keeps getting more and more subspecialized. So, a cardiologist is kind of a generalist of cardiology, and, you know, now there's these four subspecialties of cardiology.

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Q. Okay.

A. It's pretty amazing. It's pretty ridiculous.

Q. What -- what does an interventional cardiologist do? Can you just describe that?

A. Yeah, interventional cardiology is the part of cardiology that does procedures on patients, you know, and that's really the first thing they started doing were angioplasties. You know, in the mid '80s, that really was origin of interventional cardiology, fixing blocked arteries, working through a pinhole.

That was the beginning of interventional cardiology, the field of interventional cardiology, but now it's gradually expanded to where interventional cardiologists do many different types of procedures, all minimally -- from a minimally-invasive approach. That's really what defines it.

Q. When you were practicing as an interventional cardiologist, did you use medical devices?

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A. Absolutely, yeah.

Q. What -- what sorts of medical devices?

A. Well, certainly balloon angioplasty catheters; stents, you know, the wire mesh cylinders that we put in to scaffold open blood vessels; atherectomy devices, which is where you go in and carve out the plaque, you know, and remove it; closure devices, you know, where you go through pinholes to close defects in the heart, you know, holes between to atria and the ventricles, and congenital abnormalities that are repaired now through pinholes.

All of these things replaced the need to have to have open-chest surgery. And now, of course, the -- another big one are the -- literally the percutaneous valves. I mean, literally replacing valves just through pinholes. I mean, those would be the major areas of interventional cardiology.

Q. Turning now to the entrepreneurial aspect of your background.

In 2001, you mentioned that you started --

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A. Yes.

Q. -- a medical device company.

What medical device company was that?

A. It was called Velocimed, V-E-L-O-C-I-M-E-D.

Q. What types of product or products did --

A. We made --

Q. -- Velocimed make?

A. We made three different medical products. One was what's called an -- and at the time this was really the first one. It's something called an embolic protection device.

One of the risks of doing angioplasty was sometimes you could go in, inflate a balloon to dilate an artery, but debris could break off and go downstream, you know, and if that happened, you could have damage downstream. Like if that would break off and go to an important place, like the brain or the kidney or something like that, that was one of the areas of complications.

So, we created a little basket that could catch that that we'd put in first and

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then did the angioplasty, and if anything went down, you would catch it.

Second product was something called a PFO closure device, which was an umbrella -- a little umbrella, miniature umbrella, that you could put through a pinhole and go in and close a hole between the right and left atrium of the heart.

And the third one was what we called a navigation catheter, because one of the things that would start cardiologists from being able to do a procedure is if they couldn't get to that spot, you know, through the curving blood vessels. So, we made a catheter that could be, using a joystick, directed to go around sharp curves.

St. Jude bought all three of those products in the year -- I started the company in 2001. St. Jude bought that company in 2005, and all three products are still -- are still being sold around the world today. That was the first company.

Q. Were those products approved for sale by the FDA?

A. All of them eventually achieved worldwide approval, including US.

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Q. And what -- are you aware that the FDA classifies medical devices in one of three separate classes?

A. Yes.

Q. And what -- what class of device were the three devices sold by or created by Velocimed?

A. Well, the embolic protection device and the PFO closure device were Class 3 devices. The three classes are, you know, literally 1, 2, 3, where 3 is the -- the highest level of sophistication, and, therefore -- you know, or potential risk and the most novel, which then means it needs the most testing.

Class 1 devices are typically devices that are the least amount of risk, and they're often -- they are often devices that are copies of other devices that are out there, that have predicates, and everything's known about them, and it's just kind of like one more copy doing the copycat thing. You know, they can get a label as a Class 1. Label 2 is somewhere in between.

The navigation device was Class 2.

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Q. Got it.

A. But then my second company Lutonix, L-U-T-O-N-I-X, that was a Class 3 device too.

Q. When did -- did you found Lutonix?

A. I founded both of these companies.

Q. And when -- when did Lutonix come into being?

A. 2007, and CR Bard bought that company in 2000 -- in December of 2011.

Q. What product did Lutonix create?

A. We made an angioplasty balloon that had a drug coating on it, and so, when you did the -- so, when you would do the angioplasty, the drug would transfer to the blood vessel wall, and the drug would then prevent the artery from re-narrowing, you know, after you did the angioplasty.

Q. Is that angioplasty balloon approved by the FDA?

A. Yes.

Q. And you mentioned that it was a Class 3 device?

A. 3, yep. First -- first drug-coated angioplasty balloon in the world to be approved by the FDA. We got approval in 2012.

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Q. Where are you currently employed Dr. Wahr?

A. Holaira, H-O-L-A-I-R-A.

Q. And when did you join that company?

A. I joined it in September of 2012.

Q. Did you found that company as well?

A. No.

Q. Who founded Holaira?

A. An individual called Marty Mayse, and co-founded along with another person, an engineer named Steve Dimmer. They were co-founders.

Q. When you joined the company in 2012, was it called Holaira?

A. No, the company was originally founded in 2008. That's when Marty Mayse and Steve Dimmer founded the company. So, when I joined the company, it was already four years old, and the original name of the company was InterventionalPulmonarySolutions [sic], all one word. They -- they called it IPS for short, to abbreviate it.

Q. Let's talk about the Holaira -- well, actually, I should first ask you: What's

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your role at Holaira? What do you do there?
A. I'm the CEO.
Q. And have you always been the CEO?
A. Yeah -- well, since they hired me, yeah, for the last three years, yeah.
Q. Okay. Let's talk about the -- the products that Holaira creates.
What -- what is the product that Holaira creates?
A. We -- we have a product that's called -- the name of the product is dNerva, and what it is is it's a -- we use it to do a procedure called targeted lung denervation, and the -- and the system that does it we call the Holaira Lung Denervation System.
Q. Can you describe for me what components there are to the Holaira Lung Denervation System?
A. Yes, there are -- there's a -- the system has a console. The console does really three -- three things that are important. It has a -- it's the generator for the energy, you know, RF energy, radio frequency energy, which is the power we use to -- for the therapeutic effect, which I'll describe

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in a minute.
It also has the pump in it, because we have to circulate cold water, you know, through the catheter while we do it. It also has a -- so, therefore, it also has a chilling -- a chiller in the console. And then, of course, it has a user interface, you know, which is a software program.
The console runs the dNerva catheter, and the catheter is the active -- you know, is the therapeutic part of the product, and the dNerva catheter is used by an interventional pulmonologist. The interventional pulmonologist takes the dNerva catheter, and he puts it through the working channel of a flexible bronchoscope, you know, and flexible bronchoscopes are something that interventional pulmonologists have used for years.
It's still -- it's a flexible catheter that goes down -- you know, in through your mouth, down the trachea, and they can look around inside the lungs with this, but our catheter goes through the working channel inside that bronchoscope,

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and when -- when the interventional pulmonologist puts it down, he can position it in both the right mainstem bronchus first and then the left mainstem bronchus. You can actually do it in either sequence.
That could be -- the working end of the catheter has an electrode on it, which is used to deliver the energy, and when that electrode is positioned correctly inside the right or left main bronchus, the energy can be turned on, so that it delivers thermal energy to the wall of the -- the main right -- the right and left mainstem bronchus that can denature the nerves that go to the lung permanently, so that those nerves are interrupted.
And what's great about that is those nerves are what -- if you -- if you interrupt those nerves, it allows the airways to dilate, open.
Q. Let's just back up for a second.
You -- you referred to something called a bronchus?
A. Yes.
Q. What is the bronchus?

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A. Anatomically, your main airway. It comes from your vocal cords. It's called the -- down to -- its first branch point is the trachea, and that's the big airway. You can feel it, you know, right -- right in your throat.
When that comes -- when that gets down into the middle of the chest, it branches into two main -- two large branches, and those are call the right and left mainstem bronchus, and then the mainstem bronchus, in turn, branch into multiple other airways, and then they keep subdividing into -- and goes down into all of the little billions of airways, you know, out in the lungs.
Q. Okay. So, the -- the bronchus -- the mainstem bronchus is outside of the lungs?
A. Yes, you're not technically in the lungs yet.
Q. Okay. And then the bronchus stems out from the mainstem bronchus and goes into the lung fields?
A. Yeah, it goes -- it goes -- basically, you have the mainstem bronchus, and then you

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have secondary bronchi and then tertiary. You know, it's just dividing and dividing and dividing.

Q. And describe for me, again, where the -- where within in the body the dNerva catheter is used?

A. In the right and left mainstem bronchus, in just those first major divisions.

Q. Okay.

A. It never goes down into the lung fields.

Q. And the -- what -- what condition is Holaira seeking approval from the FDA to treat with this device?

A. Well, COPD, Chronic Obstructive Pulmonary Disease, is the disease process, and in patients that have COPD, COPD is characterized by overactive nerves, you know, that -- that are causing -- and these overactive nerves cause the airways to be constricted, you know, kind of in spasms, so to speak, and up until this point in time, the way COPD patients have been treated are with inhalers.

And, of course, you see this on television all the time. Spiriva is the

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leading selling pulmonary drug in the world, maybe the first or second leading selling drug of any kind in the world. You know, the inhaler that you see people who can't breathe puff on.

And what that -- the way that inhaler works, it goes down, and it literally is trying to block the nerves, you know, that go to the lungs so the airways can open up. What we're trying to do, we're going in, and we're -- by using this RF energy and the right and left mainstem bronchus, we're trying to ablate those nerves, so that we -- so that we can permanently -- get a permanent dilation, so that you have a permanent bronchodilation. So, it would become an alternative therapy to drugs or even an additive, where we actually know it would be an additive to drugs, and there's a reason for that, to benefit.

Q. Let's talk about the -- a little bit more about the medical procedure in which the Holaira Lung Denervation System is used.

You mentioned a name for the

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medical procedure itself. What was that again?

A. Targeted lung denervation.

Q. Okay. And where is targeted lung denervation performed? Like in what kind of setting?

A. It's in a hospital, a pulmonology procedure room. It's in a special room that -- where hospitals do these bronchoscopies procedures.

Q. What -- who performs the procedure?

A. An interventional pulmonologist.

Q. What's an interventional pulmonologist?

A. Well, it goes -- it kind of goes back to the same thing about when I talked about interventional cardiologist.

Until recently, until literally a couple years ago, the -- the highest level of certification within the field of pulmonary was a Board-certified pulmonologist, and these were doctors that did bronchoscopies, you know, just that were diagnostic, you would go and look around to see what was in the lungs.

But in the last -- over the last

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number of few years, similar to what had happened 15 or 20 years ago in cardiology, a new field has arisen of interventional pulmonology, where pulmonologists can do additional training to become skilled at actually doing invasive procedures, and this group are what we refer to as the interventional pulmonologists, and to be -- and that is a fully now recognized Board certification-required subspecialty of pulmonology, where they literally have to do a two-year fellowship after training all the previous stuff, do two additional years of interventional pulmonology and then pass the Boards to be a card-carrying credentialed interventional pulmonologist, and they -- they do everything -- well, I shouldn't say they do everything.

They do an awful lot. They do a lot of different procedures now just through the bronchoscope that used to require open-chest surgery. You know, the same story again like what happened 20 years ago in cardiology, and they'll do everything from putting in stents to dilating blocked

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airways to resecting tumors to, you know, removing foreign bodies, just lots of things.

So, we as a -- our procedure, targeted lung denervation, is one of an array of things that they do.

Q. You mentioned that -- how many of -- roughly how many interventional pulmonologists are there in the United States, if you know?

A. Today, there are about 150 roughly, about 150. So, you can kind of think of it as each state -- if all states were average size, there would be two or three in a state.

It will grow. You know, the -- the fellowship programs that train them are turning out about, you know, seven or eight new ones a year, you know, in the US, you know, the specialized places that are formally training them. So, that number will -- I expect will slowly grow.

Q. Okay. Let's discuss a little bit how the company changed names from IPS to Holaira, and to assist with the -- the discussion, I'll mark and hand you an exhibit.

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A. Sure.

(Exhibit Number 1 was marked.)

BY MR. HANSEN:

Q. Dr. Wahr, you've been handed what's been marked as Wahr Exhibit 1.

Do you recognize this document?

A. Yes.

Q. What is it?

A. This is -- these are documents that we put together not long after I took over as CEO to help guide, you know, our renaming process, you know, and also, you know, some Board presentations that -- where we actually conveyed some of this information to our Board of Directors --

Q. Okay.

A. -- about why we were doing it.

Q. And was this a presentation present to the Holaira Board of Directors?

A. Yes, this first one here, the open session of the Board meeting. I mean, this was part of the Board meeting where -- you know, Board meetings have generally two parts.

They have what's called an open session, where key company executives are

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included; and then there's what's called a closed, where it's just me with the Board of Directors period. You know, that's the part where you talk about things like compensation and confidential stuff that you wouldn't want to have other people sitting in on.

Q. During the --

A. Open session.

Q. -- open session, if you'd flip to page -- the twelfth slide in, which is -- has the Bates number on the bottom right, Holaira 627?

A. Yep.

Q. There is a -- appears to be a discussion about branding activities?

A. Yep -- yes.

Q. What was the purpose of this -- the inclusion of this slide in the presentation?

A. Well, I was -- I introduced it -- as you noticed on the first page, the company was still called Innovative Pulmonary Solutions at this time, but I wanted to -- and I -- this -- this was really my first Board meeting, you know, because I was hired in

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September, and this was December, and so, this was my very first Board meeting that I led, and I had already decided by that point that I wanted to change the name of the company, and this was my starting to socialize that concept to the Board.

Now, you have to realize this was a Board of Directors that had been with this company for four years, you know, and so, they were pretty -- you know, they were very familiarized with the previous name, and so, I just didn't want to come in and say I'm changing, so how I'll commonly do things is I'll introduce something and socialize it and then -- then come back with a recommendation at the next Board meeting.

It's a good way to run a company, by the way, if you ever do this. Don't blind-side your Board with just radical stuff in the cold.

So, this was socializing the concept that I was working my way towards rebranding the company, which is a way of saying, we're going to change the name, we're going to change the Website. You

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know, we're going to -- you know, our materials that are shown publicly, you know, we're going to rethink.

Q. Why did you want to move away from the IPS name?

A. Well, this was my third time around the track, you know, with a company, and so, while I don't consider myself a marketing person, I'm used to working with marketing people, and I do believe what they say.

And, to me, there were a couple -- there was a few problems with Innovative Pulmonary Solutions.

Q. What were those problems?

A. Well, one is -- is that marketing people will tell you that they really -- they would never recommend the name of a company that goes much more than two or three syllables. Innovative Pulmonary Solution had 11. It's too many words, you know, to be efficient, you know.

And the second thing is is that it was so long that you couldn't even fit it into some URL boxes. You know, when you go to type in your emails and stuff, it

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wouldn't fit, and, you know, you'd run out of space, and then you were just stuck on a lot of forms. I found that particularly irritating.

The third thing was it was just kind of a sentence. You know, it wasn't really a unique word. Marketing people and branding people want you to create your own unique word. Because it wouldn't fit into URL addresses, the company started calling itself IPS for short, which is a three-letter acronym, but the problem with IPS was, one thing, marketing people don't like acronyms, but, number two, it was already trademark. I mean, in fact, it's trademarked by about 15 people worldwide for all kinds of different things. There's absolutely nothing unique about IPS, you know, as a three-letter thing -- thing out there.

So -- so, for all of those reasons, I felt we needed -- and since the company -- I had just become the new CEO, part of becoming the new CEO was we were going to move the company -- we decided we'd move the

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company from Seattle, where it had been the first four years, to Minneapolis.

So, we were moving the company, and it's going to be a new entity, you know, here in Minneapolis, of which the people in Minneapolis didn't even know -- you know, there was no memory of the old name. So, it was the perfect time to change the name.

Q. On the -- on slide 12, the third bullet point down says: Need image that demonstrates we are different from competition, relevant to the target audiences and credible.

Do you see that?

A. Yep.

Q. What was meant by "demonstrates we are different from competition"?

A. This is a Class 3 device, first time -- and it's very novel, first time anything like this has ever been done in humans. You want a name that is not confused with anything else, you know, that is totally unique, that will -- a new word -- a new word, you know, created that will become the image of your product, you know, that no physician will

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ever find confusing.

You know, that's fundamental -- that's what's fundamental. You don't -- you know, when the Google people decided to have a -- a search engine that you could find anything on the Internet in 100th of a second, they wanted a word that nobody had seen before, and that's -- they created the word "Google," which now everybody thinks has been around for a century, when, in fact, it's only been around for ten years, because it was brand new. That's what you're trying to do.

Q. After this Board meeting, did the -- did the IPS continue in the process of rebranding?

A. Yes, the Board -- when I introduced this, the Board gave me -- they said, yes, we're interested in having this done, go do it.

Q. And what -- did Holaira, or IPS at the time, retain any third-party entities to assist in that process?

A. Yep, it's on here. You know, I had already started the process, you know, with a marketing consultant named Lorraine Wright on the slide, and Lorraine, in turn, was

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working with a marketing company called Six Degrees.
Q. Okay.
A. Lorraine is not an employee of Six Degrees. They are two different things. So, Lorraine is our marketing person basically.
MR. HANSEN: Let's mark that exhibit.
(Exhibit Number 2 was marked.)
BY MR. HANSEN:
Q. Before we get into this next exhibit, Dr. Wahr, you mentioned that Lorraine Wright is not an employee?
A. Right.
Q. Although she's not an employee, is she treated like -- as if she's an employee with respect to her job function?
A. Yes, she's our -- she's our only marketing person we have. She does 100 percent of our marketing activities, which, because we're still a pre-revenue company, clinical stage, as I call it, we don't really have a need yet for a full-time marketing executive.
So -- so, that's why she's still at consultant status. I would estimate she

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probably spends about 50 percent of her time working with us, but she has some other clients, but she's our sole person, and she carries a Holaira business card, has a Holaira -- has a Holaira email address, and she -- she is our -- she functions as if she's a full-time employee. All marketing-type questions, you know, that flow through -- or inquiries from the Website flow through her.
Q. Let's turn to Exhibit 2.
A. Okay.
Q. Have you seen Exhibit 2 before, Dr. Wahr?
A. Yes.
Q. What is Exhibit 2?
A. These are the materials that were put together by Six Degrees working with Lorraine Wright that were literally the -- the documents we worked off of in our company meetings as we started through a methodical process of -- of considering various alternatives for renaming the company.
Q. If you turn to the third slide in, which is Bates number Holaira 48, there's a slide

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entitled: Naming Considerations?
A. Yes.
Q. The first bullet point says: The new name must be shorter, simpler, fewer syllables.
What is that in reference to?
A. That's in reference to our previous name of Innovative Pulmonary Solutions that had 11 syllables.
Q. Okay. If you turn to Holaira 50, which is another couple of slides in, it's entitled: Metrics for Naming?
A. Yep.
Q. Can you describe what the purpose of this slide is?
A. Yes, this is a -- this was a slide that Six Degrees put together. I would say that it's pretty much a boilerplate that marketing firms use for how you -- you know, it was not unique to us. It was unique to what they do every time regardless of the client, in terms of, when you start through, how do you invent a new name or new word.
By the way, this is kind of -- I found this -- found this fascinating when I got into this. There is no word in

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Webster's Dictionary that's not trademarked. So, you can't name the company anything of a word that exists. There -- whatever the thousands of words, they're all trademarked.
So, the only way you can create a new trademark is to come up with a brand new word. Isn't that amazing? There are more trademarks, in fact, than there are words in the dictionary. So, you have to -- I thought that was pretty -- pretty amazing, you know, which is why you've got to get creative people to do this stuff.
Now -- now, but these things here are -- are what they say are -- are the different categories of how you think about it, you know, as you go about it as a team, you know, association, different, clear, pronounceable, memorable --
(Reporter clarification.)
THE WITNESS: The categories were product association, different, clear, pronounceable, memorable, positive and available. All the categories that you needed to -- you had to be able to have all of these apply at the end of the day.

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BY MR. HANSEN:
Q. And we may have discussed this already, but why was it important -- why was it an important metric for the name to be different from the competition?
A. Because we had -- we have a novel, first-in-the-world-ever-done product. We want -- we wanted no confusion that this had any similarity to anything else. It had to be totally unique, the word, to imply the fact that this also was a totally unique product.
Q. If you turn to the slide just before the one that we're on, there's an identification of a number of products that treat pulmonary conditions, correct?
A. Yes.
Q. Why were you considering these other entities and names in this process?
A. Because we knew that these were names of products that interventional cardiologists were already familiar with and using, and we wanted to make sure that ours was -- you know, was not similar to any of them. I mean, again, getting back to the different

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and unique category.
Q. I think you said interventional cardiologists --
A. Oh, did I say that?
Q. -- do you mean pulmonologists?
A. I continue to do that, because I used to be one, but, yeah, interventional pulmonologists. Glad Marty isn't here.
Q. If you turn to slide Holaira 56, it's entitled: Naming Categories?
A. Yeah -- yes.
Q. Can you describe for me what -- what this slide reflects and what these naming categories mean?
A. Well, the way the marketing team helps stimulate growth -- I mean, group-think is to provide categories, you know, of concepts, and they generally name, when they -- you know, in doing this, they come up with anatomic things or physiologic things or structures, you know, that are -- that have something to do with what you're doing, you know, and so, therefore, in terms of what we do, it's -- it's pretty easy for them to go nerve, air, pulmonary, lung,

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respiration, open -- you know, "open" meaning open airway.
So -- and then they -- and then you take each of those one by one and start to create words that might be related or convey or be related to these general categories.
Q. So, for example, air-centric?
A. Yes.
Q. What -- what impact does a word being air-centric have on the word itself?
A. Well, I mean, each of these would -- would commonly -- you know, would -- you work around that. You start with that concept of, say, air, and then you work around it and try to mold words, you know, that might encompass it.
Q. Okay. And why -- if you know, why were these specific categories identified as potential categories for words?
A. Because they related -- they all had something to do with our procedure, you know, what we do.
Q. If you turn -- we're going to jump around just a little bit, but if you turn to the third from last page of the slide deck,

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which is Holaira 111, there's a short list of names.
Were there more names considered than just this -- this short list?
A. Oh, yes, yeah, yeah. I mean, there were -- yeah, there were many, and in all of those categories, there were a lot in each category.
What these -- what these marketing people do, they sit down and -- and they provide you with a list to stimulate, you know, all various renditions within these categories.
Q. What -- what process was used to take the longer list and winnow it down to the shorter list?
A. We had -- we had a group meeting, where we had -- there were really -- there were really, you know, a smaller group of people, four or five people, that -- that put the most time into this.
It was myself; it was Marty Mayse; it was Steve Dimmer, the other founder; Lorraine Wright, we probably put in relatively more time in discussion, but

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there was also a larger group of some of the other employees in the company that were also brought in to comment on -- on just gut reaction, you know -- you know, what kinds of things that started to shake out as people's favorites.

Q. Let's flip back in the slide deck to Holaira 65, which is an air-centric name, and the name is Holaira?

A. Yep.

Q. Ultimately, this is the name that the company selected, right?

A. Yes.

Q. Why did the company select the name Holaira?

A. The -- there were -- there were several reasons that this one, as more and more discussion went, rose to the top, and the one that I liked the best was that the fundamental reason why I think our product is going to be so exciting in the marketplace is because the current standard of care for this disease is -- are these inhalers, these drugs, you know, that people breathe -- breathe in, but what's known by both -- all physicians know this, and the

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pharmaceutical companies themselves acknowledge it, is that the Achilles heel of drugs that they don't talk about for treating lung disease is that, when they breathe these drugs in -- and they can only be given by -- by inhalation. They can't be given by swallowing pills, and there's reasons for that pharmacologically, but the drugs will go preferentially into those small airways that are wide open, and they won't go to the ones that are blocked, the drugs.

So, the drugs, it's estimated, achieve only maybe at best 50 percent of the potential benefit that could be had if you had a way to get -- get -- you know, get, in effect, in all of the airways, not just the open ones, but that's also not really known for sure. People debate that.

Some people say it's less even, you know, but -- so, drug therapy is really only treating part of the lung, you know, when these -- when it goes in, but it's still better than nothing.

Our real benefit of our therapy by

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going in and denervating the nerves in the right and left mainstem bronchus, and 100 percent of all the nerves that go to the lungs go in -- are in the walls of that right and left mainstem bronchus. By denervating, we could dilate all the airways, the whole thing, the whole lung, and so, I love the concept that we'll be the first company that can truly deliver therapy to the whole lung, you know, and so -- and, whereas, I would say pharmaceuticals deliver therapy to only part of the lung. We're the whole lung.

And so, the whole focus here was on whole, you know, W-H-O-L-E, but the marketing people, being the clever way they are, said, let's spell it H-O-L, because it's pronounced exactly the same way and it's clever. Now, you're looking like a unique word, as opposed to W-H-O-L-E, which is a word that everybody recognizes.

So, shorten it to Hol, H-O-L. So air to the whole lung, and that really started to resonate to people as really a -- a cool thing.

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The second thing was that -- was that, as the people started doing reviews, there's very, very few things in all of medicine, you know, whether it's drugs or procedures or -- or words or anything that begin with the letter H. H is really rare. So, it was extremely unique, and the other thing is is that we also found out the word holo, H-O-L-O, is actually another word that you can find out there, and actually its derivation is also whole, you know, actually. So, if you drop the W in -- you know, in languages, H-O-L-O, also means whole. So, it really came through that it was air to the whole lung and -- and really unique.

The one thing that -- that I had a little hesitation about, which actually also makes it -- made it really unique, but was that we struggled with, and when we tested this around with different people, people had -- when they said, what do you think when you see this word? Well, you know, there's a derogatory street slang term called ho, you know, like that person's a

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ho.

Anyway, but that is a negative term, and -- and so, we struggled with the fact that it would have too strong, you know, a differential, you know, in terms of a word being thrown into -- into medicine, and so -- but the marketing people actually kind of liked that, because it gave it more of an edge, you know, of uniqueness. And, by the way, nobody really thinks that, you know, as our testing -- they really see "whole," you know, is where they go.

Q. Can you describe for me how the company pronounces its name?

A. Yeah, it's Hol, H-O-L, hyphen, second syllable, is air, A-I-R, and the last syllable is A. Three syllable, where it's H-O-L, then second syllable A-I-R, another syllable A, and we really differentiated -- we really wanted that differentiated all the way to the point that on the -- that, on the logo, we put an umbrella of dots over the word A-I-R to differentiate the word "air" and separate it from the syllable H-O-L, so there was no -- no -- to really call that

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out, to get the word Hol on there, H-O-L, and you've seen the -- it's on the business cards. You've seen the logo.

Q. Going back to the -- the short list of -- of names, there were -- at the back of the slide deck, there are a number of names that Holaira ultimately did not go with.

A. What page?

Q. 111?

A. Oh, 111.

Q. Yep. For example -- well, first, let me ask you this: There are a number of names that have Xs in the different columns.

A. Yeah.

Q. Would we take that to mean that the names with Xs are in the running or out of the running?

A. In the running.

Q. Why didn't Holaira end up using the name Vitaira?

A. Well, you know, there were people that liked Vitaira in the group, but -- but one of the things that -- that became a differentiator on that one was that, for whatever reason, and these things tend to go in trends, but

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if you look at the last four or five years of medical device company names, there have been a lot of Vs. There's a lot of companies out there that start with V, and so, for that reason, that was a discriminating -- that was probably one of the main reasons why we moved away from that at the end of the day. In discussion, in fact, my first company had begun with a V, Velocimed, and that was a bias to me. I didn't want to do another V company.

Q. And why didn't you select Apaira?

A. Again, I think that it was a -- there are A companies out there, and we thought that -- we thought that there was another company out there called Alero, you know, that we thought that looked a little close to, so we thought Apaira was close to some other competitors.

Q. And when you say "Alero," are you talking about the product sold by Boston Scientific?

A. No.

Q. What --

A. It's a pharma -- it's a pharma drug.

Q. And how do you spell that?

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A. A-L-E-R-O, I think is the name of it -- is how it's spelled.

Q. Ultimately, you went with one of the air-centric names, Holaira?

A. Yes.

Q. Why did you go with an air-centric name?

A. It was a category people liked the best. I mean, it is the fundamental basis of what we do is to improve airflow to the lung. I mean, it's -- it's the closest.

Q. Were you aware of any other company name, product names or trademarks, that had the word air within it when you made the decision to go with an air-centric name?

A. Yes, there's a lot -- there's a lot of "airs" out there.

Q. When you say "there's a lot of airs out there," what do you mean?

A. I mean, there's a lot of companies -- I mean, there's a lot of products out there where the syllable A-I-R is a part of the name.

Q. And what -- what field are those products?

MR. WALZ: Objection, foundation.

BY MR. HANSEN:

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Q. Do you know -- you mentioned that there's a lot of words out there with "air" in it?
A. Yes.
MR. WALZ: Objection, foundation.
MR. HANSEN: To what?
MR. WALZ: How does he know that there are a lot of products out there that have "air" in it? You can lay the foundation. I don't know how he knows that.
MR. HANSEN: He just testified that he knows it.
MR. WALZ: How do you know it?
BY MR. HANSEN:
Q. Okay. Dr. --
A. I've seen them a pulmonary meetings and generally follow the literature.
Q. Okay. So, you work at a company that has a product -- is developing a product in the pulmonary space, correct?
A. Yes.
Q. And through going to meetings in the pulmonary space, you're aware of other company names?
A. And product names, yeah -- yes.
Q. And is that how you're aware of other --

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A. Yes.
Q. -- names using the word "air"?
A. Yes.
Q. And are those other product names that are in your mind in the pulmonary space?
A. Yes.
Q. Can you recall any of them?
A. Xolair.
Q. What does Xolair do?
A. It's a drug.
Q. What -- are you aware of the term "Alair"?
A. Yes.
Q. Sold by Boston Scientific?
A. Yes.
Q. Why -- what consideration, if any, did you take of that name when deciding to choose the name Holaira?
A. Say that again.
MR. WALZ: If I could, you took a piece of paper out of your coat pocket, and you now seem to be referring to it.
THE WITNESS: Yes, there's -- I have four names of companies with "air" in it that I think are really good examples.
MR. WALZ: Okay. That's fine. You

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can use it.
THE WITNESS: Okay.
BY MR. HANSEN:
Q. Dr. Wahr, what -- what examples are on that piece of paper?
A. Well, there's Singulair, Xolair, VitalAire and Alere, A-L-E-R-E.
Q. Turning back to my question about Alair, the product sold by Boston Scientific, what consideration, if any, did you take of the existence of that name when deciding to use the name Holaira?
A. We wanted to make sure that we were very different from any other word, and I would say that that fell into that category. You know, we were -- we -- as you saw in the previous slide, we got the list of the other leading -- or I shouldn't say leading, but the known products that are used by interventional pulmonologists, and so, we looked at that entire list and said, are we different than all of these words, you know, and we were -- we were confident we were different from all of these words, because nobody had anything that looked like Hol,

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H-O-L, at the beginning of the word.
Q. What -- why did you want to be different from Alair?
A. Because eventually -- because we have a unique product, and we want our -- our physicians, who are our main customers, to -- to have no confusion about what we are doing.
Q. Let's turn to the -- the development of the Holaira products.
I understand, and certainly tell me if I'm wrong, I understand that the Holaira product is not commercially available in the United States?
A. It's a clinical stage company.
Q. When you say "it's a clinical stage company," what do you mean?
A. It's not approved for use, you know, for commercial sale.
Q. And what -- what process is the company undertaking to become approved for commercial sale?
A. We're doing a -- we're working through clinical trials, you know, human clinical trials, and the -- the process that -- that

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we're doing is we're doing a three -- three-stage development program, which has began with Phase 1 clinical trials. We finished that.

We're in what are now called Phase 2 clinical trials, and then if our data looks good in the Phase 2 trials, we'll move on to what's called Phase 3 clinical trials, which would be the pivotal trial. We're in the middle of Phase 2 right now.

Q. Why is the company undertaking that process?

A. Well, the product is -- because the product is novel and has never been done before, you need to be very careful, you know, as you work your way through the development process, that you make sure that -- that your product is safe, first of all, and the way that's done in the eyes of the regulatory authorities is they will approve you to treat a small number of patients.

You treat those patients in the Phase 1 trial, and then if that looks good, then they'll give you a larger number of patients you can treat, which is basically Phase 2 trials. If that data looks good,

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and basically Phase 1 and -- Phase 1 trials are really focused on safety. You know, they -- the way this works, they first want to know that you're not going to hurt anybody, and then if they -- if you pass that bar, then you move on to where your trials will be big enough that you can start to, in followup testing, show that you're actually beneficial, you know, but safety comes first, and then you move on to the benefit part.

So, Phase 2 kind of attempts to re-corroborate the safety issue of Phase 1 in a large enough pool of patients that you might be able to start to get a signal to understand your -- your efficacy of a mark. The other thing -- the other part about Phase 2 trials is that you also are allowed to start exploring some other parameters, such as dose and, you know, some other variables about your product.

Q. You mentioned --

A. But when you get to Phase 3 -- when you get to Phase 3, you need to have your final procedure and your energy dose and

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everything has to be defined and done, and then that's it, and that would be the trial in which eventual approvals are based is Phase 3.

Q. You mentioned earlier that there are three classes of products within the FDA?

A. Right.

Q. What class of product is the Holaira System?

A. It's Class 3, and generally Class 3 products are the products where you would go through this type of extensive clinical testing program.

Class 1 products, for example, may not need any clinical testing at all. I mean, they could literally just -- in humans, they could just be developed on a benchtop somewhere and get approval.

Generally, Class 2 products are somewhere in between. Generally, they require a -- some human testing in a trial, but for sure Class 3 products require, you know, an extensive development program since it's never been done before, and you've really got to prove that safety thing before -- before they're going to let it go

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out on the market.

Q. What indication is being sought for the Holaira products?

A. Patients of -- patients with moderate to severe COPD.

Q. Let's turn now, Dr. Wahr, to the use of the name Holaira.

When did -- when did the name Holaira start being used by the company, if you recall?

A. Probably in the first quarter, first quarter of 2013. We -- yeah, plus or minus a month or two, somewhere in there.

Q. And how is the -- how is the Holaira name -- how is the Holaira name used?

A. We use it -- I mean, it's the name of the company. It's on the building. It's -- it's on our business cards. It's the name on our Website, and it's -- and it's the name on -- you know, on the product.

You know, I mean, it's the Holaira Lung Denervation System. It's on the console, and it's -- we use it on our slide template -- our PowerPoint slide template that we use when we present abstracts and

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our scientific data. I mean, it's the name of -- it's the name of the system and the name of the company, so it's on that stuff.

Q. At what events, if any, has Holaira presented to physicians?

A. Publicly, public presentations of our company to date has only happened one time, and that was -- our coming-out party for public presentation was at the European Respiratory Society meeting in Munich, Germany last fall.

That's the only public presentation, you know, at a -- at a trade show, and we did not have a booth. It was -- we were start of the scientific agenda. We had abstracts that were accepted for presentation, and we did one evening symposium, you know, where we summarized our product for the -- you know, for the attendees.

Q. And what were the attendees? Who was the audience at that --

A. Primarily interventional pulmonologists, as well as, in general, pulmonologists. That would -- that made up the majority of the

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audience, and then there were industry people there as well.

You know, whenever a new product is kind of like shown at one of these meetings, other companies that are in the space always come out of interest as well, as you would expect.

Q. When I asked a few questions ago, you made a distinction, I think, between public and private presentations?

A. Yes.

Q. Has the company done any private presentations?

A. Yes. Oh, yes. I mean, everybody -- you know, all of our physicians, who are investigators in our clinical trials, you know, obviously, have had private presentations, and not only private presentations, but have gone through training, extensive training, on how to use the device, and so, there's been meetings with that group of doctors, but we also have meetings with physicians in private that are other key opinion leaders, KOLs, that stands for key opinion leaders, leading physicians

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in the interventional pulmonary space, to get their feedback and input and, you know, reaction to what we're doing.

So there's been a number of those meetings as well.

Q. And in those meetings you use the name Holaira?

A. Yes.

Q. Approximately how many private presentations would you say that Holaira has had?

A. Over -- since I have been CEO, those types of meetings, fairly formal meetings, I would say at least 50.

Q. And are those to interventional pulmonologists in the United States or elsewhere?

A. Both Europe and the United States.

Q. And within the United States, how many of those types of meetings have you had?

A. Probably about a third of them have been with US docs; two-thirds of them with European physicians.

Q. Has --

A. Our US -- our US -- we have no US clinical sites yet. You know, we're hopeful we'll

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have some later, you know, in the not too distant future.

Q. Has Holaira used the name Holaira in any press releases?

A. Yes.

Q. Do you know about how many in the last, what is it, three and a half years?

A. Since I have been CEO, there have been five press releases.

Q. What's the general topic of those press releases, if you recall?

A. The majority of the -- most of them were related to finance. It's common to do press releases after you raise money successfully, and -- or to announce, say, a key new employee hire, and then I think one of them was on -- you know, was announcing our clinical data that was going to be shown at the European Respiratory Society.

Q. Has Holaira --

A. They're -- they're all posted on the Website.

Q. Has Holaira clinical data been published in any medical journals?

A. Yes. Yeah, our Phase 1 -- our first

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clinical trial now is published in a peer-reviewed journal called Thorax.

Q. Has -- are you aware of any confusion between Holaira and Alair?

A. None.

Q. Are you aware of any confusion between or about Holaira's affiliation or lack of affiliation with Boston Scientific?

A. None.

Q. Let's turn now, Dr. Wahr, to the sales process for the Holaira product.

First, who is the -- the target customer for the Holaira products?

A. The interventional pulmonologists.

Q. Why is that?

A. Because our product will -- will be labeled that it is only for use by an interventional pulmonologist. That will be -- and then even if you are a Board-certified pulmonologist, just that by itself is not sufficient. You will also have to go through and finish the formal training program.

Q. I'll dig into the formal training program in just a minute.

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A. Okay.

Q. But you mentioned it will be labeled?

A. Yeah.

Q. What -- what does that mean, "it will be labeled"?

A. Well, the -- the -- when the FDA approves a product, they -- they define in the label who the patients are that -- what are the -- what are the inclusion criteria that the patient must have in order to be a candidate for the therapy.

In our case, it would be moderate to severe COPD, you know, and what the testing parameters are that make that patient formally eligible to get the therapy; and, number two, what are -- what are the requirements for a person to be -- to use the device.

You know, what is the training qualifications, you know, for a person to be able to use the device. Those are defined as part of a product being approved by the FDA.

Q. What -- what sales -- I understand the product isn't commercially available as of yet, but does the company have some sense as to what sales process it intends to employ when the product becomes commercially available?

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A. Yes. I mean, yes. I mean, we don't have a detailed plan, because that's out there in the future, you know, a number of years, but -- but at a high level, yes, and our plan for commercialization will be a direct sales force.

Q. And what do you know by a direct sales force?

A. Meaning --

Q. Can you describe that?

A. Meaning we will not use distributors or other third-parties to -- to sell our product.

Q. And how would the -- what's the concept of how the direct sales force would go about selling the product?

A. It would be -- it would be direct from -- I mean, it would be direct to the interventional pulmonologists. It would be direct point-of-contact with the interventional pulmonologists.

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Q. You mentioned that that's a few years out.

Do you have an estimate as to how far out that is?

A. The -- the --

Q. I should have asked a more clear question.

[redacted]

Q. You mentioned that training --

A. Yes.

Q. -- will be required to be able to use this product?

A. Yes.

Q. What -- can you describe for me what that training is?

A. Yes, the -- the training program, it isn't just a training program for a commercial product. The training program is also a

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requirement even to just be doing our clinical trials at this point in time, you know, where we -- anybody who's going to be an investigator for us has to go through the formalized training program, which consists of both didactic, where it's slide presentations, you know, to instruct them in every aspect of how to use both the console and the device itself, you know, how to run them, how to position them.

But there's also a -- you know, so, there's a mechanical part to it, but there's also an education about patient selection, you know, entry criteria, you know, for patients and also how the patients are followed up afterwards. So, it's a comprehensive, you know, all -- all parts of it.

And in addition to the didactic presentations, there's also a hands-on training process, where -- where they use the device on a mannequin, as well as on a human cadaver, in a cadaver lab.

Q. And who provides this training to physicians?

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A. The company. We do, the company. You know, our -- our technical team.

Q. Company employees?

A. Company employees, yeah.

Q. Is there any support provided by company employees at actual patient cases?

A. Yes. After -- after completing the training program, there is company support at all of the clinical cases, 100 percent of them, and when -- and we anticipate that that will go on throughout the entire clinical program, and the term they use for this is proctoring, you know, in the medical world; and there will be a requirement that comes in at the time of approval by the FDA for when the product goes commercial will be a specific designation for how many cases after completing the training program a physician has to be proctored before he can really be turned loose, you know, to just do these cases in an unsupervised fashion.

And where that number is going to be for the number of required proctored cases, isn't settled yet. I mean we'll learn more about that as -- as we go through

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the whole clinical program, but I would expect it will probably be in the three-to-five-case range.

Q. How -- how, if at all, are patients targeted for Holaira marketing?

A. We don't do any -- any -- any marketing to patients, you know, at this point. Patients have the potential to become aware of us, you know, by finding -- you know, by discovering it, you know, by reading journals or going on the Website or things like that, but we don't actively do any marketing to patients.

Q. What is the -- does the company have a sense as to what the price-point for the Holaira System will be once it's commercially available?

A. Well, it will be -- there's two components to it. There would be the catheter, you know, the dNerva catheter, will have -- which is a disposable, one-time use, and will have one price; and then the console, which can be used repeatedly, you know, on many cases, will be another.

So, there will be two purchased

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things; the console and the catheter. [redacted]

Q. Are you familiar -- in your time as an interventional cardiologist, and as well as based on your experience selling Class 3 medical devices, are you familiar with the process for purchasing Class 3 medical devices?

A. In hospitals?

Q. Correct.

A. Yes.

Q. What -- who makes the decision to purchase a Class 3 medical device?

A. Hospitals have what's called a purchasing department, and the purchasing department is really the one that -- they issue the checks. I mean, that's where -- that's the key thing you got to get past, and they have formalized processes for how they make the decisions.

And, in general, the process starts

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when a physician tells the purchasing department that there's a new product, or in some cases, the product's been around, but just hasn't been there on -- you know, available before, a physician makes a request that they would like to have a product, you know, put in the inventory or on the shelf, so to speak, at the hospital.

And then when that happens, a process starts in the purchasing department, where -- where it's basically an application process where you have to educate the purchasing department about what it is, what its merits are, you know, what its potential benefits are, you know, to the patient.

It's usually initiated by -- it can be initiated by any one of the physician, you know, specialties in the hospital. Generally purchasing departments then consider other things. They might -- they might ask for feedback from other specialties that would know about this. They -- they would -- they may look for medical society recommendations. They would -- they also would look very carefully

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about whether there's reimbursement available.

Sometimes hospitals will decide this is a great product, but because no reimbursement is available from the insurance companies, they still won't put it on the shelf. You know -- you know, and that's when it sometimes comes into conflict, you know, hospital -- I mean, physicians versus hospitals that -- you know, if the physicians want it, and the hospital doesn't want to buy it, those are interesting discussions, but it's a pretty involved process.

Q. And why does the direct sales force -- or why is the intent for the direct sales force at Holaira to work directly with interventional pulmonologists as opposed to the purchasing department?

A. It's both a combination of the complexity of the product, plus the cost, and -- and that's too much to really rely on a distributor for.

You know, distributors are really -- in my experience, do best with

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commodity-type products, you know, that don't require education. You know, like for example, if you had a -- there's 30 different hip prostheses out on the market, and they're very -- and in many cases very hard to differentiate one from another. You know, a company might give a distributor, here's our hip prostheses, go out there and sell it, and -- because it's not a technical sale, and if -- but as products get more and more sophisticated, it's a -- you need your own highly, highly educated company representative to go in there and -- and educate -- you know, educate that physician, and then the hospital too.

I mean, you know, the company reps get involved in the -- in the education part even working with the purchasing departments as well.

Q. And what -- what role does the physician have in the decision to purchase the product?

A. He is a -- he makes a recommendation, but his recommendation is essential to starting the process. I don't know of any situation

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where a hospital purchasing department would just, on their own, decide they want to put something on the shelf. That wouldn't happen.

Q. With a Class 3 medical device, is it possible for a patient to purchase the product?

A. No.

Q. Why not?

A. It can't be sold. It's not for sale to -- to patients. It's for sale only to -- to the hospital's purchasing department on the recommendation, you know, of the pulmonologist.

Q. How would a patient who comes across the Holaira name, once the product's commercially available, how would that patient possibly get the treatment?

A. They would have to -- they would have to identify a hospital and physician that -- that are approved to do the procedure and go to that medical center.

MR. HANSEN: Why don't we go off the record. I'll go through my notes and see if I have any other questions for you,

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Dr. Wahr.
THE WITNESS: Okay.
(Break taken.)
MR. HANSEN: Dr. Wahr, I have no further questions for you at this time. Thank you.
Do you want to take a break, or do you want to --
MR. WALZ: Yeah, if we can take a break, and I can just kind of get some docs ready, and then we'll come back.
(Break taken.)
EXAMINATION
BY MR. WALZ:
Q. Dr. Wahr, are you ready?
A. Yes.
Q. Okay.
MR. WALZ: I'll just have you mark this first.
(Exhibit Number 3 was marked.)
BY MR. WALZ:
Q. So, Dr. Wahr, you've been handed what's been marked as Deposition Exhibit Number 3. This was a document produced by Holaira.
Do you recognize that document?

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A. Yes.
Q. And if we turn to page -- well, it's Bate-numbered 1392?
A. Yes.
Q. At the bottom there, there's -- next to signature, Dennis W. Wahr; is that correct?
A. Yes.
Q. And that is your signature?
A. Yes.
Q. And --
A. Well, I don't see a signature, but it's my name typed.
Q. That's an electronic signature, correct?
A. Oh, okay. All right.
Q. And you signed this application, correct?
A. I -- I probably did, yes. It's three years ago.
Q. So, it's possible that someone else signed this application?
A. No, I just don't see my signature on here.
MR. HANSEN: Objection to the form.
THE WITNESS: No. Yeah, so, you know, I mean I'm taking your word for it that somebody printed this up with numbers.
BY MR. WALZ:

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Q. Right. And you reviewed this application before you signed it, correct?
A. Yes.
Q. And you understood what you were applying for when you sign the application, correct?
A. Yes.
Q. And all the information in this application was correct as of December 19th, 2012 when the application was signed, correct?
A. I haven't -- it's been a long time since I've read it, but I assume it was.
Q. So, if we look at the -- let's see here, if we look at the page Bate-numbered 1391?
A. Yes.
Q. You will see, next to International Class 10, there's a description that reads: Medical devices, medical apparatus and instruments?
A. Yes.
Q. Now, that identification was at some point amended; is that correct?
A. I don't know if we amended this or not. I don't know the answer to that.
Q. Okay.
A. I don't understand your question.

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(Exhibit Number 4 was marked.)
BY MR. WALZ:
Q. So, you've been handed what's been marked as Deposition Exhibit Number 4. This is a printout from the United States Patent and Trademark Office test database, and next to the Goods and Services heading, there's a description that reads: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases.
Do you see that?
A. Yes.
Q. And that's different from the description we saw on Exhibit 3, correct?
A. In that paragraph that starts, "International Class;" you're referring to?
Q. Correct, on Exhibit Number 3.
A. Well, it's -- I mean, the wording is slightly different, but it's saying the same thing. I mean, it's -- it's a device for treating obstructive -- it's a medical apparatus and instrument. The one -- the one on the right is -- looks like it's more detailed.

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Q. And when you say "the right," you're referring to Exhibit Number 4, correct?
A. Right.
Q. And looking at Exhibit Number 4, does that description accurately reflect the device that will be used in connection with the Holaira mark?
A. Yes, this is appropriate.
Q. Okay. And you have no intention of further amending or clarifying the identification description that you see in Exhibit Number 4, correct?
A. Not at this point in time.
Q. Okay. And just for a purpose of clarity, I think when you were discussing before the difference between dNerva -- the mark dNerva --
A. Yes.
Q. -- and the Holaira mark, you mentioned that dNerva will be used as the product name, but that Holaira is going to be the company name?
A. Holaira -- Holaira is the company name. The system, you know, the whole system that consists of the console, you know, and the

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catheter, we call the Holaira Lung Denervation System.
Q. Okay.
A. But the catheter, the catheter that's disposable, the part that goes through the bronchoscope, is the dNerva catheter.
Q. I see, okay.
(Exhibit number 5 was marked.)
BY MR. WALZ:
Q. So, you have been handed what's been marked as Deposition Exhibit Number 5.
Do you recognize this document?
A. Yes.
MR. HANSEN: I'll just object it's outside the scope of the direct examination.
MR. WALZ: We'll bring it within the scope.
THE WITNESS: Yes.
BY MR. WALZ:
Q. You do recognize it? Okay.
And if we flip to the second to the last page again at the bottom, we see next to signature, Dennis Wahr?
A. Yes.
Q. That is your signature?

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A. Yes.
Q. And you did sign this application as well?
A. Yes.
Q. Okay. And then if we look on the third page from the end, next to Class 10, we see medical devices, medical apparatus and instruments, correct?
A. Yes.
(Exhibit Number 6 was marked.)
BY MR. WALZ:
Q. So, you have been handed what's been marked as Deposition Exhibit Number 6. This is a printout from the United States Patent and Trademark Office test database. It's for the dNerva mark, and, again, next to the heading Goods and Services, we see medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases?
A. Yes.
MR. HANSEN: Objection, outside of the scope of the direct examination.
BY MR. WALZ:
Q. And similar to the Holaira mark we saw before, comparing the Exhibit 6 to

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Exhibit 5, the description was amended, correct, to what appears on Exhibit 6?
MR. HANSEN: Same objection.
You can answer.
THE WITNESS: Okay. The words on the -- on the Exhibit 6 are -- are slightly different than here, but, again, it appears like they're saying the same thing.
BY MR. WALZ:
Q. And if we compare Exhibit 6 with, I believe -- what was the Holaira -- I can't remember the number -- test page? So, is that Exhibit 4?
A. 4.
Q. So, if we compare what's in Exhibit -- the identification in Exhibit 6 with the identification of the goods description in Exhibit 4, those descriptions are the same?
A. They look the same.
MR. HANSEN: Same objection.
BY MR. WALZ:
Q. Okay. And if you look at Exhibit 1 --
MR. HANSEN: Do you mean Exhibit 3, Brad?
MR. WALZ: I'm sorry, Exhibit 3.

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BY MR. WALZ:
Q. If we look at the page that's numbered 1391, underneath that International Class 10, there's an Intent to Use, and it says: The applicant has a bona fide intention to use the -- or use through an applicant's related company or licensee the mark in commerce or in connection with the identified -- on or in connection with the identified goods or services.
Do you see that?
A. Yes.
Q. And at the time you signed this application, you had the present intent to use the Holaira mark in connection with a medical device for treating obstructive lung diseases, medical apparatus and instruments for treating obstructive lung diseases, correct?
A. Yes, after going through all the appropriate regulatory approvals.
Q. Right.
A. Yeah.
Q. And after -- if we look at Exhibit 5, that's the dNerva application, looking on page --

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page 4, under that International Class 10, we have that same "intent to use" language?
MR. HANSEN: Object, outside the scope.
You can answer.
THE WITNESS: Yes.
BY MR. WALZ:
Q. And the dNerva application was filed, if we look at the second to the last page -- or was signed, I should say, on April 25th, 2013, correct?
A. Yes.
Q. And then if we look at Exhibit 6, and we look at the filing date, it was actually filed the same day as well, correct?
A. Yes.
Q. And that's approximately four months after the Holaira application, which is Exhibit 3, was signed by you, correct?
A. Yes.
Q. So, my question is: How could you have a bona fide intent to use the Holaira mark if four months later you filed an application for the dNerva mark with the exact identification of goods descriptions?

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A. Well, the -- we decided that we wanted a distinct name for -- for the actual catheter itself versus the system, and so, we wanted one more -- we wanted a different -- it's different parts of -- it's a specific part of the bigger system.
You know, the system is the Holaira Lung Denervation System, but the disposable product is its own entity. It's different.
Q. So, is the dNerva application, the ID in that dNerva application, misdescriptive of the goods that will actually be used in connection with the mark?
MR. HANSEN: Object to form and outside the scope.
BY MR. WALZ:
Q. I guess I'm trying to find out if one of these applications is misdescriptive of -- of what you intend to use the mark for?
A. Well, the -- the description is general. I mean, they both apply. I mean, it's accurate for both. It's a correct designation for both -- both marks.
Q. But you said dNerva would be used in connection with the disposable catheter, not

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a medical device for treating obstructive lung diseases?
A. Well --
MR. HANSEN: Object to the form.
THE WITNESS: Well, the catheter is part of the system. So, it would be used in the same way, and you're confusing me. I'm not sure where you're going with that.
BY MR. WALZ:
Q. That's okay. We can move on.
A. Okay.
Q. So, the Holaira device can be used to treat chronic asthma, correct?
A. In theory, if we -- if we chose to go that way, in theory, it could, yes. It would be a completely new clinical development program.
Q. And that is an area that you're thinking of expanding into, correct?
A. Not right now.
Q. But it is something that you have --
A. It's theoretically possible that we could make that decision at some point in the future.
Q. Right. But you've promoted that to

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potential investors and -- and identified it as a potential area?
A. Yes.
Q. And you market -- as you testified, you market the device to physicians, right, interventional pulmonologists?
A. Interventional pulmonologists.
Q. Okay. And you're marketing that as a treatment for COPD, correct?
A. Correct.
Q. And that term is understood as an umbrella term, right?
A. COPD, yes.
Q. And so, under that umbrella, would include a condition such as chronic asthma, correct?
A. No. COPD is generally -- is generally felt to have two major components. One would be emphysema, and the other would be chronic bronchitis.
Asthma is a -- is felt to be a distinct different disease process. We -- we do not believe that -- we certainly believe that asthma does not fall under our label indications.
MR. WALZ: Okay. Would you mark

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that as 7, I believe.
(Exhibit Number 7 was marked.)
BY MR. WALZ:
Q. So, you've been handed what's been marked as Deposition Exhibit Number 7. It is a printout from the medical-dictionary.thefreedictionary.com. These are definitions concerning COPD.
If you turn to page 5, and I guess it flows over into page 6, and if you look at page 6 first, this is -- well, the definition that begins on page 5 for COPD that turns over -- or spills over onto page 6 at the bottom, this is a definition from McGraw-Hill Concise Dictionary of Modern Medicine.
Do you see that at the bottom?
A. Yes.
MR. HANSEN: I'll object to the document as containing hearsay.
BY MR. WALZ:
Q. So, if you turn to the first page -- or on page 5, that final dictionary definition for COPD states: Chronic Obstructive Pulmonary Disease, Pulmonology, an umbrella term for a

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group of usually progressive lung disorders with overlapping signs and symptoms, including asthma.
Do you see that?
MR. HANSEN: Object, hearsay, foundation.
THE WITNESS: I'm not sure what page -- I can't seem to find the page you're on.
BY MR. WALZ:
Q. So, at the top of each page, there are page numbers; do you see that?
A. Oh, okay. What page?
Q. Page 5, and that definition begins at the bottom and spills over.
So, I was saying, do you see on page 5, that last definition of COPD?
A. Yes.
MR. HANSEN: Same objections.
BY MR. WALZ:
Q. And it says: Chronic Obstructive Pulmonary Disease, Pulmonology, an umbrella term for a group of usually progressive lung disorders with overlapping signs and symptoms, including asthma?

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MR. HANSEN: Same objection.
BY MR. WALZ:
Q. Do you see that?
A. Yes.
Q. Okay. And then if we turn to page 6, we see another definition of COPD at the bottom. This is from the Gale Encyclopedia of Medicine, and it says: A term used to describe chronic lung diseases, like chronic bronchitis, emphysema and asthma?
MR. HANSEN: Same objections.
BY MR. WALZ:
Q. Do you see that?
A. Yes.
Q. Do you have any reason to dispute these definitions?
A. I think that our -- our definition of Chronic Obstructive Pulmonary Disease is what we -- our indications on our labelling indication are for chronic bronchitis and emphysema. Asthma is excluded. We don't treat asthma.
Q. Okay. But a doctor would understand, or a physician would understand, the term "COPD" according to these medical dictionary

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definitions to include asthma?
MR. HANSEN: Objection, form, foundation and hearsay.
THE WITNESS: No, I don't agree.
BY MR. WALZ:
Q. But the Holaira System will compete with the Alair System; is that correct?
A. No, it will not.
Q. You said though that the Holaira System could possibly treat asthma?
A. We have no clinical development program for asthma, and every pulmonologist, as well as interventional pulmonologist, sees them as distinctly different diseases, and the only way we could treat asthma would be if we started over from scratch with a completely new Phase 1, you know, feasibility study in asthma patients, which, at this point, there has been nothing initiated to start such a program. It would be unaffordable for us to do that.
Q. To start --
A. An asthma program.
Q. -- an asthma program?
A. Yes.

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Q. But you are marketing that to your investors as a potential area of growth, correct?
A. If -- in the future, if a new -- if a new -- if another company were to buy Holaira, they could make a decision to start an asthma program in theory, but understand that it would be going all the way back to the starting point and starting at point 0 in terms of that, and -- and the earliest commercialization date for us to have a label indication for asthma, if somebody wanted to start that today, might be 2025.
I mean, it's way out there, and it would be another $100 million development program, which has not started at this point.
(Exhibit Number 8 was marked.)
BY MR. WALZ:
Q. Showing you what's been marked as Deposition Exhibit Number 8.
Do you recognize this document?
A. Yes, yes.
Q. And what is this?
A. This is a presentation that I gave at the Piper Jaffray Healthcare Conference.

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Q. So, if you turn to page 2, in the heading, it says: Holaira, Treatment For COPD and Asthma, right?
A. Yes, yes.
Q. Okay. And if we look at page 11, it's Bate-numbered 12 --
A. Yes.
Q. -- we see a -- a chart of revenue projections, and then at the bottom of that chart, there's a box?
A. Yes.
Q. And it says: COPD and asthma indication split 70/30 in 2022?
A. Yes.
Q. And then if we turn to page 12, Bates-numbered 13, and again we see at the top in the heading, this is a competitive landscape, and in the chart, there is, in the second box below company product, Holaira, and then if we go to the right under COPD, there's a checkmark; under asthma, there's a checkmark; and under emphysema, there's a checkmark.
Do those checkmarks indicate that the Holaira device can be used --

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A. Yes.
Q. -- to treat these conditions?
A. Yes, it could, yes.
Q. And then if we move below the Holaira box, there's an entry for BSC that says, formerly Asthmatx/Alair; and under that, we see a checkmark in asthma?
A. Yes.
Q. And that indicates that the Alair System is used to treat asthma, correct?
A. Yes.
Q. And Boston Scientific is identified on a chart where you've labeled it competitive landscape as a competitor, correct?
A. Yes.
Q. And if we turn to the very last page -- I'm sorry, page 17, Bates-labelled 18, we see a slide labeled -- titled: Series D Financing Highlights -- I'm sorry, are you there?
A. Yeah, I know it. Go ahead.
Q. And underneath the bullet point, Milestones Through 2016, there's a subpoint for asthma as part of the clinical heading?
A. Yes.
Q. And that there's six months of data from the

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asthma feasibility study.
Does this mean that you've already started a feasibility study for the use -- use of the Holaira device to treat asthma?
A. No, this was -- this was a slide done, because at the time we were raising our $40 million, we did not have an asthma program. We wanted to leave open the possibility that if one of our investors -- if our lead investor wanted us to start one, that's when this could be available, but, in fact, when we closed the $40 million financing, our new investors did not want to do an asthma program.
So, therefore, this has completely dropped off the radar screen, if that makes sense to you.
Q. Yep.
A. So, our clinical program is emphysema and chronic bronchitis.
Q. Let's talk a little bit about targeted lung denervation.
So, I think, as you testified before, targeted lung denervation, TLD, is the generic name that you have created for

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your procedure, correct?
A. Yes.
Q. And that's similar to what, you know, Boston Scientific had done with bronchial thermoplasty?
A. Exactly.
Q. And TLD is a procedure that will require a patient's informed consent, right?
A. Yes.
Q. And with respect to the informed consent obligations, one of the things that will have to be discussed is the nature of the procedure, correct?
A. Yes.
Q. So, as you described before, the use of a bronchoscope, the use of a catheter to place a energy emitter within the main bronchi, and then the administration of energy in that main bronchi, correct?
A. Correct.
Q. And there will have to be a discussion with the patient that the Holaira device will be used as part of that TLD treatment?
A. Absolutely.
Q. And in discussing the nature of the

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procedure, you'll also have to explain to the patient -- or the doctor will, I should say, that, as you described, the treatment is intended to denervate the nerves, that it will not have -- it's not intended to avoid any of the smooth muscle of the bronchi, correct?
A. Yes.
Q. And, in fact, there is no effect to the smooth muscle through targeted lung denervation, correct?
A. That -- that's what we believe, yeah.
Q. So, then you will have to discuss the risk and benefits with -- or the physician will, with respect to TLD, and you'll also have to discuss any alternatives, correct?
A. Yes, yes.
Q. And an alternative would be bronchial thermoplasty?
A. For what we do? No, bronchial thermoplasty is not indicated for COPD -- I mean, for chronic bronchitis or emphysema.
Q. But that -- so, bronchial thermoplasty, though, has an effect on the smooth muscle tissue?

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A. Yes.
Q. And --
A. That's what they say, yes.
Q. And we talked about how COPD is an umbrella term, and that chronic asthma is underneath that umbrella?
A. You -- you've completely manufactured that. No interventional pulmonologist buckets asthma with emphysema or chronic bronchitis. Those are -- the two things that we treat are completely different from asthma period. That's why we have them in the three columns. Boston cannot -- is not an label to treat chronic bronchitis or emphysema.
Q. But there are variations to asthma, isn't there? You can have acute asthma?
A. There -- there is a classification of asthma, where -- where, in the severest form, some of the pulmonologists will say that it starts to look like COPD, but -- but those are not -- those patients are not included in our protocol or will be on-label.
Q. So, a patient --
A. They're different.

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Q. But a patient with chronic asthma, though, if they were to talk to a physician about TLD, a physician would have to have a discussion at least about what treatment is available for asthma, correct?
A. No, because there's --
MR. HANSEN: Object to form.
THE WITNESS: -- there's no label indication for what we do.
BY MR. WALZ:
Q. Is there ever any operable use?
A. Huh?
Q. Does operable use happen at all?
A. It never -- it never happens with a non-commercially-approved product. [redacted]
Q. Oh, right, obviously. We're not -- yeah, right, I guess, yeah, to bring --
A. I mean, if they want to go to jail, they can do that if they want.
Q. Yeah, we're talking about a product that is not yet commercialized, right?
A. Right.
Q. We're talking about an intent to use

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trademark application.
So, just so I understand, as part of a -- of a doctor's informed consent obligation, you're saying that a patient that they're advising with respect -- that has chronic asthma would not have to be told that, in addition to targeted lung denervation, which could be used to treat their condition, there's a separate procedure called bronchial thermoplasty, which could be an alternative to targeted lung denervation?
MR. HANSEN: Object to the form, lack of foundation.
THE WITNESS: Absolutely not. You're really mixed up on this. You know, the -- an asthma patient under any circumstances, no doctor in the world would tell an asthma -- would tell an asthma patient that TLD is an alternative therapy for what they have.
TLD at this point is an experimental therapy only being tested in chronic bronchitis and emphysema that, [redacted] they will get an approval, and

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there's nothing even in the works.
They would have absolutely no obligation to tell a patient that.
BY MR. WALZ:
Q. Okay.
A. And even if they did, it would be totally unavailable.
Q. Okay. So, what -- yeah, I guess, again, we're talking -- again, you're not using the mark -- the device -- so, I'm not talking about -- we need to think about in terms of when your product is actually available and gets approval, [redacted]
A. Right.
Q. So, when you're both in the market --
A. [redacted]
Q. [redacted] So, the two treatments are now actually available.
TLD is available to persons?
A. For asthma -- I mean, excuse me, TLD for chronic bronchitis and emphysema, right?
Q. COPD, right?
A. No.
Q. That's --
A. No, if you are choosing to arbitrarily use

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COPD as this higher bucket, like your thing says, then -- then it's an inappropriate umbrella, because we are only going to be approved for emphysema and chronic bronchitis.
(Exhibit Number 9 was marked.)
BY MR. WALZ:
Q. Handing you what's been marked as Deposition Exhibit 9.
If you turn to the second page?
A. Yep.
Q. This is -- it's titled: Six Degrees Confidential Backgrounder.
Do you recognize this document?
A. What's the date of this one? October 12. Yeah, this one would have been created about a week after I started, but I recognize a lot of the things in here. I'm not sure I've seen this before, but go ahead.
Q. Okay. So, if we look at just even the executive summary, and this was -- let me back up.
I mean, the intent of this document was to educate Six Degrees, who was your marketing firm that was retained to help you

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with the naming process, right --
A. Yes.
Q. -- to understand your company?
A. Yes.
Q. Okay. So, in the executive summary, there, it says that: IPS is a system -- the main objective of the IPS System is the development of a commercial product to enable a new therapeutic procedure, TLD, which will improve respiratory function for moderate to severe COPD patients?
A. Yes.
Q. And it doesn't say chronic bronchitis or emphysema, correct?
A. You know --
MR. HANSEN: Feel free to review the entire document before you answer questions about it.
THE WITNESS: Yeah, I think you're taking this out of context. Our COPD definition that we use throughout the entire company is COPD is chronic bronchitis and emphysema. It is not asthma. Our clinical programs, you know, make it clear that asthma is not included.

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But, by the way, could our device eventually at some point be used to treat asthma? The answer is yes, and I've said that already, but we're not developing it for that. So, that's the answer to your question.
You know, so --
BY MR. WALZ:
Q. Okay.
A. -- I mean, you're arguing over the semantics of this, but I can promise you, in interventional pulmonology, we can bring in 20 experts, and they all see asthma, chronic bronchitis and emphysema as three completely different entities.
Now, most people traditionally would put just two of them under COPD, chronic bronchitis and -- chronic bronchitis and emphysema under COPD. That's what you see under every commercial on TV when you see Spiriva advertised. And they put asthma over here in a different category, because its mechanism of action is different, and it's a different disease process.
Q. Right.

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A. And -- and that's -- that's how we use it, but the point is is that I'm not denying the fact that, if we ever -- if a future owner or investor or something wanted to start an asthma program, our device could -- could do that, and that's why it appears in there. I'm just simply saying we're not doing that right now.
Q. Right.
A. And -- and if somebody decided to do it, it would be way out there.
Q. Okay.
A. And I don't understand what that has to do with the trademark anyway.
Q. Yeah, this is just -- this is just -- you know, in all of the documents I've seen produced by Holaira --
A. Yeah.
Q. -- reference is always made to COPD. So, that's why I just wanted to get some clarification as, you know -- and you even describe it on your Website as an umbrella term?
A. Over --
Q. So --

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A. -- over CO -- over emphysema and chronic bronchitis, yes.
Q. But as we saw in some of those medical definitions, you know, asthma has been included as -- under the umbrella?
A. I will go on the record though as the vast majority of people in this space of the experts separate asthma under a completely separate umbrella and not under the COPD umbrella. That's my statement, but it doesn't matter to this anyways.
Q. That's your opinion, right?
A. Right, it's my opinion, and it's clearly the -- the opinion of the vast majority of people that this is how they would classify it.
(Exhibit Number 11 was marked.)
BY MR. WALZ:
Q. So, you have been handed what's been marked as Exhibit 11. This is an email from Mark Laverman to Lorraine and also yourself. You are identified as a recipient, and this email attached two PowerPoint presentations.
One is the messaging blueprint, and the second is the -- the naming -- what is

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it called? Is it the naming concept?
So, you previously testified that you were targeting only interventional pulmonologists with respect to your sales efforts?
A. It was the primary target.
Q. So, it's not the only target?
A. It's not the only target.
Q. Okay. What are some of the other targets?
A. Well, if you're putting -- if you wear my hat as the CEO, my primary targets are, number one, the customer, which is interventional pulmonologists. Number two, you're -- you're also targeting with what you do the investors. That's critical for a company at our stage.
You know, those would be -- you know, those would be the two most important, so --
Q. Anyone else?
A. Well, I mean, you're also -- I mean, you're also -- you're also going to target general pulmonologists. You're going to target all of the physicians, you want to have an awareness of that, and you want to target

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future acquirers, you know, of the company, you know, so, you know, you want to put out to -- you want to reach out to all of them, and you're happy to have patients gain awareness of it as well.
Q. So, you won't reach out to patients?
A. Not directly, no.
Q. Okay. If you turn to the page Bate-numbered 538, there's a title there of the report called Audience -- Audiences?
A. Which page?
Q. It's Bate-numbered 538.
A. I don't seem to have numbers on mine.
Q. It's on the right -- lower right. Yeah, you got it right there.
A. Oh, here we go.
Q. Yep. So, it's titled, Audiences; you see that at the top?
A. Um-hmm.
Q. And at the far right -- actually, let's back up.
On the left, we have the medical community, which you talked about, right, the interventional pulmonologists, et cetera; the financial community is to the

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right of that medical community box; and then at the far right, we have consumers?
A. Yes.
Q. So, you're -- you're telling me you're not going to target consumers?
A. Our -- our marketing -- our marketing efforts right now are clearly related to the interventional pulmonologists. I mean, we certainly don't want to hide this from the patients. We do no active marketing to patients, but eventually down the line -- down the line, if you have a novel medical therapy, you wouldn't -- I mean, you're not going to block that from happening, but you're not going to spend money on it.
Q. You will not spend money on even down the road on --
A. On actively reaching out to the patients. I mean, this will be something with -- I mean, patients with COPD and emphysema come to their pulmonologist, and then -- and they -- it's that pulmonologist then that will be the key decision-maker, the interventional pulmonologist.
Q. So, will you make any -- once you're

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commercialized, will you make any marketing material that potentially could be distributed to a consumer?
A. We have no plans at this point. Would we do the stuff like what the pharmaceutical companies do with direct TV marketing, I actually don't believe in that.
Q. But you'll -- so, it's not in your plan to create any marketing material, but is it a possibility?
A. Maybe for some big company in the future. They might choose to do it. It would be a highly ineffective way to do it I think, but --
Q. To market the Holaira?
A. To go direct to patients with a product that only a highly sophisticated subspecialist -- I don't really see St. Jude and Medtronic going to customers to market their particular type of aortic valve prostheses, you know, when they -- when the patient would have no idea what the right prostheses is for the aortic valve. It is possible? Sure. It's not the primary target.
Q. But the Holaira device is tied closely to

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TLD, correct?
MR. HANSEN: I'm just going to lodge an objection. You're -- sometimes you pronounce it Holaira, and sometimes you pronounce it Olaira [ph]. I just want to make sure that you're meaning Dr. Wahr's company.
MR. WALZ: Well, as you know, I mean, there's no right way to pronounce a coined term. So --
MR. HANSEN: But I think the issue is you're switching back and forth. I just want to make sure that --
MR. WALZ: Yeah, Olaira, Holaira, I mean, that's referring to -- yeah.
MR. HANSEN: Okay.
BY MR. WALZ:
Q. So, let's look at Exhibit Number 2, and if we turn to the page Bate-numbered 111?
A. Got it.
Q. So, it's true that, at all times during this naming and branding process, that your company, you were aware of Boston Scientific's Alair System, correct?
A. Yes.

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Q. And this page that we're looking at, 111, is the list of short names, as you testified to, and you've also testified that you needed to get creative people involved, you needed to select a name -- a new name that was completely unique, correct?
A. Yes.
Q. Unlike any other, correct?
A. That was the goal.
Q. Yet the Holaira mark that you ultimately, you know, settled on has the L-A-I-R string included in it, correct?
MR. HANSEN: Form.
THE WITNESS: Yes.
BY MR. WALZ:
Q. And that is the same string of letters that's in the Boston Scientific Alair mark, correct?
A. Yes.
Q. And you also testified that, based on attending meetings, that you were aware of a lot of "air" marks, although when you referenced the piece of paper that you took out of your pocket, there were only four names on there, correct?

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A. Four names on there, yep.
Q. And Xolair, you mentioned, was a drug?
A. Yes.
Q. Singulair is a pharmaceutical?
A. Yes.
Q. VitalAire is a pharmaceutical?
A. Yes.
Q. And Alere, L-A -- A-L-E-R-E, is that a pharmaceutical as well?
A. Yes.
Q. Do you know how prevalent the use is of the Xolair mark?
A. It's -- I don't. I don't know what their market share is, no, but it's displayed prominently at -- you know, on trade booths, you know, at pulmonary meetings, so I assume it's being used commercially quite a bit.
Q. Does the Holaira device compete with Xolair?
A. No.
Q. Does it compete with Singulair?
A. No.
Q. Does it compete with VitalAire?
A. No.
Q. And how about Alere?
A. No. It doesn't compete with bronchial

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thermoplasty either.
Q. I didn't ask you that question, sir.
You also mentioned that you had received from consumer feedback about the Holaira mark in -- in connection with the prefix "Ho," that you -- you had received some -- some negative --
A. No.
Q. -- potential negative feedback?
A. No, we didn't -- that was an internal concern when we just were talking about it, you know, but no consumer feedback.
Q. So, you did no external testing or --
A. No.
Q. -- surveys or anything?
A. That was just our internal discussion.
Q. And when you testified that there had not been any confusion, you had also testified that you're not using the mark yet in the United States, correct?
MR. HANSEN: Object to form, foundation, misstates prior testimony.
MR. WALZ: You had asked him if he had ever experienced -- or Holaira had experienced any actual confusion, and he

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said no.
MR. HANSEN: Yeah, and you added to the question, and you said that, "you haven't been using the mark in the United States." I think he said it's on their business cards, it's on their Website, it's on their letterhead.
MR. WALZ: I take that back.
MR. HANSEN: I think you misstated prior testimony.
BY MR. WALZ:
Q. Okay. So, you haven't used the Holaira mark in connection with the system, the medical device that you applied for, correct?
A. Applied for -- for to who? So, in the United States, it's on our Website. We show our business cards to US docs, you know, and we -- and, you know, we aren't treating any patients in the US, but, you know, US docs clearly know about -- know about Holaira.
Q. It's on the device yet, correct?
A. Oh, you mean on a device that we use in a clinical setting?
Q. Right.
A. But we -- well, first of all, we're not --

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no, we haven't used the device in the US.
Q. Right.
A. But it's not on there anyway, but we haven't used one even if it was.
Q. "Holaira" doesn't appear on the device?
A. I mean, not on our commercial device, no. I mean, it's projected to be on our -- on our device, you know, when we go commercial, but right now we're just using a clinical prototype.
Q. Yeah, I guess, just to clarify, when I'm asking questions about sort of the use of the Holaira mark, we both understand that it's -- you're not commercialized yet, but you're still in clinical.
So, when I'm talking about or asking these questions, I'm asking -- I'm referring to --
A. We anticipate to put "Holaira" -- the word "Holaira" on the console.
Q. Right.
A. But it will say "dNerva" on the catheter.
Q. Okay.
MR. WALZ: Can we just take five minutes, and I'll see if I've got anything

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else, and we can wrap-up.
MR. HANSEN: Sounds like a plan.
MR. WALZ: Go enjoy our 4th of July.
(Break taken.)
MR. WALZ: I've got no further questions for you, Dr. Wahr.
MR. HANSEN: And I have no further questions for you either, Dr. Wahr.
We'll read and sign. Thank you.
(At 11:40 a.m., the deposition was recessed.)

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ERRATA SHEET

Page/Ln	Correction	Reason

I, DR. DENNIS WAHR, have read this deposition transcript pages 1 - 112 and acknowledge herein its accuracy except as noted on the errata sheet.

_____
Signature

_____
Notary Public

STATE OF MINNESOTA

CERTIFICATE

COUNTY OF WASHINGTON

I, Alexis Jensen, hereby certify that I reported the deposition of Dr. Dennis Wahr on the 2nd day of July, 2015 in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the truth and nothing but the truth concerning the matter in controversy aforesaid;

That I was then and there a notary public in and for the County of Washington, State of Minnesota; that by virtue thereof I was duly authorized to administer an oath;

That the foregoing transcript is a true and correct transcript of my stenographic notes in said matter, transcribed under my direction and control;

That the cost of the original has been charged to the party who noticed the deposition and that all parties who ordered copies have been charged at the same rate for such copies;

That the reading and signing of the deposition was not waived;

That I am not related to any of the parties hereto, nor interested in the outcome of the action and have no contract with any parties, attorneys or persons with an interest in the action that has a substantial tendency to affect my impartiality;

WITNESS MY HAND AND SEAL this 10th day of July, 2015.

_____

Alexis Jensen
Notary Public

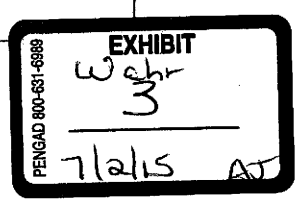
PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85806379
Filing Date: 12/19/2012

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85806379
MARK INFORMATION	
***MARK**	HOLAIRA
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	HOLAIRA
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
***OWNER OF MARK**	Innovative Pulmonary Solutions, Inc.
INTERNAL ADDRESS	Suite 105
***STREET**	3750 Annapolis Lane
***CITY**	Plymouth
***STATE (Required for U.S. applicants)**	Minnesota
***COUNTRY**	United States
***ZIP/POSTAL CODE (Required for U.S. applicants only)**	55447
LEGAL ENTITY INFORMATION	
TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Delaware
GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	010



*IDENTIFICATION	Medical devices; medical apparatus and instruments
FILING BASIS	SECTION 1(b)
ATTORNEY INFORMATION	
NAME	Barbara J. Grahn
ATTORNEY DOCKET NUMBER	24450-2001
FIRM NAME	Oppenheimer Wolff & Donnelly, LLP
INTERNAL ADDRESS	Suite 2000
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CITY	Minneapolis
STATE	Minnesota
COUNTRY	United States
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PHONE	612-607-7325
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EMAIL ADDRESS	bgrahn@oppenheimer.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
OTHER APPOINTED ATTORNEY	Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Aaron Scott
CORRESPONDENCE INFORMATION	
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STATE	Minnesota
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ZIP/POSTAL CODE	55402
PHONE	612-607-7325
FAX	612-607-7100
EMAIL ADDRESS	bgrahn@oppenheimer.com;ipdocket@oppenheimer.com

AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	325
*TOTAL FEE DUE	325
*TOTAL FEE PAID	325
SIGNATURE INFORMATION	
SIGNATURE	/Dennis W. Wahr/
SIGNATORY'S NAME	Dennis W. Wahr
SIGNATORY'S POSITION	CEO
DATE SIGNED	12/19/2012

PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85806379
Filing Date: 12/19/2012

To the Commissioner for Trademarks:

MARK: HOLAIRA (Standard Characters, see mark)
The literal element of the mark consists of HOLAIRA.
The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Innovative Pulmonary Solutions, Inc., a corporation of Delaware, having an address of
Suite 105,
3750 Annapolis Lane
Plymouth, Minnesota 55447
United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 010: Medical devices; medical apparatus and instruments
Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

The applicant's current Attorney Information:
Barbara J. Grahn and Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Aaron Scott of Oppenheimer Wolff & Donnelly, LLP

Suite 2000
222 South Ninth Street
Minneapolis, Minnesota 55402
United States
The attorney docket/reference number is 24450-2001.
The applicant's current Correspondence Information:
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bgrahn@oppenheimer.com;ipdocket@oppenheimer.com (authorized)

A fee payment in the amount of $325 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Declaration Signature

Signature: /Dennis W. Wahr/ Date: 12/19/2012
Signatory's Name: Dennis W. Wahr
Signatory's Position: CEO
RAM Sale Number: 11875
RAM Accounting Date: 12/19/2012

Serial Number: 85806379
Internet Transmission Date: Wed Dec 19 12:26:54 EST 2012
TEAS Stamp: USPTO/BAS-70.102.26.226-2012121912265408
6922-85806379-490f36f35d729fb827649d5612
4ccf1559-DA-11875-20121218180009245281

HOLAIRA

United States Patent and Trademark Office

Trademarks > Trademark Electronic Search System (TESS)

TESS was last updated on Wed Jul 1 03:21:01 EDT 2015

Record 1 out of 1

HOLAIRA

Word Mark	**HOLAIRA**
Translations	The wording "**HOLAIRA**" has no meaning in a foreign language.
Goods and Services	IC 010. US 026 039 044. G & S: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85806379
Filing Date	December 19, 2012
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	December 3, 2013
International Registration Number	1167434
Owner	(APPLICANT) HOLAIRA, INC. CORPORATION DELAWARE SUITE 105 3750 ANNAPOLIS LANE PLYMOUTH MINNESOTA 55447
Assignment Recorded	ASSIGNMENT RECORDED
Attorney of Record	Barbara J. Grahn
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

EXHIBIT
Wahr
4
7/2/15 AT

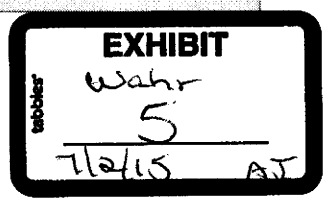
PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85914385
Filing Date: 04/25/2013

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85914385
MARK INFORMATION	
***MARK**	DNERVA
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	DNERVA
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
***OWNER OF MARK**	Holaira, Inc.
INTERNAL ADDRESS	Suite 105
***STREET**	3750 Annapolis Lane
***CITY**	Plymouth
***STATE (Required for U.S. applicants)**	Minnesota
***COUNTRY**	United States
***ZIP/POSTAL CODE (Required for U.S. applicants only)**	55447
LEGAL ENTITY INFORMATION	
TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Delaware
GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	010



*IDENTIFICATION	Medical devices; medical apparatus and instruments
FILING BASIS	SECTION 1(b)
ATTORNEY INFORMATION	
NAME	Barbara J. Grahn
ATTORNEY DOCKET NUMBER	24450-2004
FIRM NAME	Oppenheimer Wolff & Donnelly, LLP
INTERNAL ADDRESS	Suite 2000
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CITY	Minneapolis
STATE	Minnesota
COUNTRY	United States
ZIP/POSTAL CODE	55402
PHONE	612-607-7325
FAX	612-607-7100
EMAIL ADDRESS	bgrahn@oppenheimer.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
OTHER APPOINTED ATTORNEY	Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Andrew Hansen, Dennis Hansen, Aaron Scott
CORRESPONDENCE INFORMATION	
NAME	Barbara J. Grahn
FIRM NAME	Oppenheimer Wolff & Donnelly, LLP
INTERNAL ADDRESS	Suite 2000
STREET	222 South Ninth Street
CITY	Minneapolis
STATE	Minnesota
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ZIP/POSTAL CODE	55402
PHONE	612-607-7325
FAX	612-607-7100
EMAIL ADDRESS	bgrahn@oppenheimer.com;ipdocket@oppenheimer.com

AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	325
***TOTAL FEE DUE**	325
***TOTAL FEE PAID**	325
SIGNATURE INFORMATION	
SIGNATURE	/dennis wahr/
SIGNATORY'S NAME	Dennis W. Wahr
SIGNATORY'S POSITION	CEO
DATE SIGNED	04/25/2013

PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

Serial Number: 85914385
Filing Date: 04/25/2013

To the Commissioner for Trademarks:

MARK: DNERVA (Standard Characters, see mark)
The literal element of the mark consists of DNERVA.
The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Holaira, Inc., a corporation of Delaware, having an address of
Suite 105,
3750 Annapolis Lane
Plymouth, Minnesota 55447
United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 010: Medical devices; medical apparatus and instruments
Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

The applicant's current Attorney Information:
Barbara J. Grahn and Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Andrew Hansen, Dennis Hansen, Aaron Scott of Oppenheimer Wolff & Donnelly, LLP

Suite 2000
222 South Ninth Street
Minneapolis, Minnesota 55402
United States
The attorney docket/reference number is 24450-2004.
The applicant's current Correspondence Information:
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bgrahn@oppenheimer.com;ipdocket@oppenheimer.com (authorized)

A fee payment in the amount of $325 has been submitted with the application, representing payment for 1 class(es).

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The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Declaration Signature

Signature: /dennis wahr/ Date: 04/25/2013
Signatory's Name: Dennis W. Wahr
Signatory's Position: CEO
RAM Sale Number: 85914385
RAM Accounting Date: 04/25/2013

Serial Number: 85914385
Internet Transmission Date: Thu Apr 25 11:39:10 EDT 2013
TEAS Stamp: USPTO/BAS-70.102.26.226-20130425113910984874-85914385-500516f577ad1ab485c6727ddeec3c7642d6215271fbe3ee354e5bc4ea097214db4-DA-9156-20130424194812306502

DNERVA

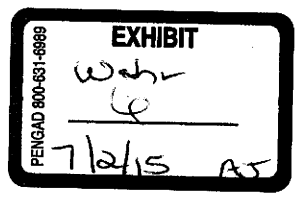
United States Patent and Trademark Office

Trademarks > Trademark Electronic Search System (TESS)

TESS was last updated on Wed Jul 1 03:21:01 EDT 2015

Record 1 out of 1

DNERVA

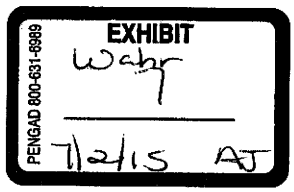


Word Mark	**DNERVA**
Goods and Services	IC 010. US 026 039 044. G & S: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85914385
Filing Date	April 25, 2013
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	April 15, 2014
International Registration Number	1181913
Owner	(APPLICANT) Holaira, Inc. CORPORATION DELAWARE Suite 105 3750 Annapolis Lane Plymouth MINNESOTA 55447
Attorney of Record	Barbara J. Grahn
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

COPD - definition of COPD by Medical dictionary

http://medical-dictionary.thefreedictionary.com/COPD

COPD



Also found in: **Dictionary/thesaurus**, **Legal**, **Acronyms**, **Encyclopedia**, **Wikipedia**.

chronic [kron´ik]

persisting for a long time; applied to a morbid state, designating one showing little change or extremely slow progression over a long period.

chronic airflow limitation (CAL) any pulmonary disorder occurring as a result of increased airway resistance or of decreased elastic recoil; the diseases most often associated are **ASTHMA**, chronic **BRONCHITIS**, and chronic pulmonary EMPHYSEMA. Called also **chronic obstructive pulmonary disease**.

Chronic airflow limitation has the highest morbidity rate of any significant chronic pulmonary disorder in the United States and is the second most common cause of hospital admissions. It is difficult to estimate its exact incidence because most diseases of the respiratory tract are not reportable and there is some confusion in definition of terms related to diseases of this type. However, the Social Security Administration reports that CAL ranked only second to heart disease as the cause of disability in men over the age of 40. The incidence of CAL is increasing and, although not all specific causes are known, factors contributing to its development and affecting its degree of severity have been identified. Heavy cigarette smoking is probably the most important factor, and others are industrial pollution, occupational exposure to irritating inhalants, allergy, autoimmunity, genetic predisposition, and chronic infections.

Prevention is best accomplished through education of the public about the hazards of cigarette smoking and air pollution and the need for early detection and prompt treatment of respiratory disorders that could become chronic in nature. The American Lung Association is particularly interested in education of lay persons in these matters and in the prevention of all types of respiratory disorders. This agency, which has local offices distributed throughout the country, is an excellent source of information about prevention and the latest developments in the treatment of respiratory diseases.

SYMPTOMS. This is an insidious disease that can develop into advanced lung damage almost before its victim is aware that the condition is serious. The early symptoms are shortness of breath upon exertion, a mild cough (sometimes called "smoker's cough"), which occurs most often in the morning, and easy fatigability that follows even minimal physical effort. Prompt treatment of these symptoms can forestall the more serious effects of extensive lung damage; however, the destruction of lung tissue and bronchial mucosa damage that has already occurred by the time these symptoms appear is irreversible.

As the disease progresses, the symptoms of dyspnea, weakness, and cough become more severe. The patient has difficulty expelling air from the lungs and the cough becomes more productive of thick, tenacious sputum. The patient looks anxious and drawn and may speak in short, hesitant sentences. Symptoms related to disturbances of the respiratory and circulatory systems and **ACID-BASE BALANCE** may appear as these complications develop.

COMPLICATIONS. Destructive involvement of respiratory structures and the resultant impairment of circulatory function can produce serious life-threatening complications. Among these are acute respiratory failure, disturbance in the acid-base balance (which can occur either as uncompensated **respiratory ACIDOSIS** or metabolic ALKALOSIS), bronchopulmonary infections, **COR PULMONALE** (the result of increased resistance in

pulmonary circulation), **pulmonary** EMBOLISM (especially if polycythemia is severe), and PEPTIC ULCER. BLOOD GAS ANALYSIS is helpful in evaluating effectiveness of blood gas exchange across alveolar walls. In severe chronic airflow limitation, the Pa_{CO_2} level is high while the Pa_{O_2} and the Sa_{O_2} levels are low.

TREATMENT AND PATIENT CARE. In general, treatment is concerned with restoring and maintaining existing lung function, relieving symptoms, and planning a program of rehabilitation tailored to accommodate the individual patient's physiologic needs, physical stamina, vocational needs, lifestyle, and personality. Specific measures of patient care are concerned with (1) initial and periodic evaluation of patient status, (2) maintenance of general health as much as possible, (3) prevention and control of infection, (4) improvement of ventilation, and (5) patient education.

Chronic airflow limitation is a disease that has no cure; its chronic nature requires an ongoing program of assessment and long-term care that is planned and revised as the patient's needs dictate. Whatever the patient care setting—acute care facility, out-patient clinic, long-term care facility, or home—the elements of care presented below are essential to the effective management of the condition.

Evaluation. Patient assessment begins with the taking of the patient's history and performing physical examination and lung function tests at the time the diagnosis is established. These measures, along with blood gas analysis at rest and after exercise, provide a baseline for periodic evaluation of the patient's status to determine the progress of the disease and the effectiveness of treatment.

When patients are informed about the purpose of the tests and therapy they are more likely to participate in the planned regimen of care and to become motivated to continue carrying out their responsibilities in the management of their illness. Those who work with the patient should clarify the goals and offer encouragement when they make progress toward those goals, no matter how slight the improvement might be. This implies, of course, that all members of the health care team have an understanding of the disease, the meaning of various test values, and the purpose of each aspect of care.

Maintenance of Health Status. It is important to communicate to these patients the concept of health status, particularly in regard to their position on the health-illness continuum. They cannot be completely disease-free or restored to their former state of health. They can, however, manage the disease symptoms for periods of time and some may even make progress toward a better state of health. For those patients who continue to deteriorate despite appropriate care, encouragement should be provided to maintain as much function as possible.

Poor appetite and the potential for dehydration are problems commonly associated with pulmonary disease. Purulent sputum, coughing, and fatigue can contribute to loss of interest in eating. Mouth breathing, increased respiratory rate, and frequent expectorating contribute to the loss of fluid.

Frequent oral hygiene and mouth care can help diminish mouth odor and unpleasant taste. A short period of rest just prior to each meal can help overcome the problem of fatigue. Meals should be spaced so that the stomach is not overloaded at any one time; five small meals, rather than three a day, can help avoid overfilling of the stomach and interference with breathing. Postural drainage and similar procedures should not be done on a full stomach, nor should they be scheduled just before a meal. Adequate hydration can be accomplished by an intake of at least 3000 ml of liquid each day. Unless contraindicated, this should include bouillon, fruit juices, and other liquids the patient finds enjoyable and refreshing.

Physical activity may be severely limited by CAL because of inadequate ventilation and decreased circulation. As with all other aspects of patient care, plans to increase exercise tolerance and promote physical activity should be designed according to the patient's cardiopulmonary status. Techniques to promote muscular relaxation and breathing control are the first step, followed by gradual increase in activity as the patient's progress and general physical condition permit.

Adequate rest is essential, but the **HAZARDS OF IMMOBILITY** must be avoided, especially in patients who are fearful that any physical activity may precipitate an exhausting episode of coughing and dyspnea. The goal is to provide sufficient rest so that the body's natural restorative processes can work, but to avoid long periods of sleeping and lying in bed during the day.

When the patient's cardiopulmonary condition is such that bed rest is prescribed, care is taken to avoid complete physical inactivity, which will only serve to increase problems of inadequate ventilation and muscle weakness. Proper positioning is essential and should be such that the neck is extended, with the chin well off the chest. Support under the thighs while the patient is supine will release tension on abdominal muscles, thereby facilitating movement of the diaphragm for deep breathing and effective coughing. The arms and hands should also be supported on pillows and positioned away from the sides to allow for maximum lung expansion without elevation of the upper chest. A foot board is placed so as to maintain good posture, promote comfort, and ensure good muscle tone in the legs and feet.

Prevention and Control of Infection. Acute respiratory infection can be fatal in patients with chronic airflow limitation. Chronic infections inflict further damage to the respiratory structures, lead to increased debilitation, and increase the likelihood of severe complications. Both acute and chronic infections produce increased secretions in the air passages, which further restrict the flow of air.

Contact with others who have an upper respiratory infection should be avoided, as should being in large crowds during the season when such infections are common. A high level of resistance should be maintained through good personal hygiene and adequate nutrition. Vaccines to guard against influenza are recommended. Patients should be taught to watch for changes in color and amount of sputum. If a change in sputum or any other symptoms of infection appear, this should be reported.

Improvement of Ventilation. It is obvious that measures to improve ventilation in the patient with CAL are of primary importance, and perhaps that is why so many ways have been devised to facilitate the flow of air to and from the lungs. Breathing is most difficult during the expiratory phase, making it difficult to remove trapped air and secretions. In addition, the bronchial walls are weakened in patients with emphysema and are subject to collapse. Health status and physical condition at the time the technique is used will affect the choice of method and its effectiveness.

Hydration is considered especially valuable in improvement of ventilation. Inhaled air should be moist so as to thin the secretions for removal and soothe the irritated mucous membranes. This can be accomplished through the use of vaporizers and humidifiers, either for environmental humidification in the patient's room or in conjunction with oxygen therapy and the administration of aerosols. Oral intake of fluids is also important. Bronchodilators, usually in the form of aerosols, sometimes as oral medications, are usually prescribed. The aerosol method of delivery depends on the ability of the patient to breathe deeply so that the medication reaches the lower segments of the respiratory tract.

Controlled deep breathing patterns are especially helpful in emptying the lungs and providing adequate ventilation. The patient with CAL is taught to expand the lower chest and to use the accessory muscles

and diaphragm to improve the breathing pattern. Performance of these breathing patterns is important because patients probably are not in the habit of breathing in the most effective manner, making optimum use of remaining pulmonary function. The patient is taught slow, controlled, and steady breathing. Respiratory effort should be concentrated on slow expiratory flow through parted or pursed lips. Pushing the air out of the lungs too forcefully can bring on collapse of the airway structures. During instruction, the caregiver watches for signs of exhaustion and warns against overdoing the deep breathing until the patient has adjusted to it. A correct breathing pattern should be coordinated with all of the patient's daily activities so that it becomes habitual and is done without too much thought.

Effective coughing does not come easily to patients with this condition. They may have experienced too many episodes in which a dry hacking cough has caused exhaustion, increased dyspnea, and prevented removal of tenacious sputum from the air passages. They must be convinced that, when done correctly, coughing can remove mucous plugs and relieve rather than produce dyspnea. Patients should be warned that explosive coughing is not very effective, can damage the airways, and can lead to exhaustion. The objective of coughing is to move secretions upward gradually so that they can be expectorated.

POSTURAL DRAINAGE is also valuable in facilitating the removal of mucus from the air passages. The various maneuvers involved in this procedure are designed to take advantage of gravity flow as a means of clearing specified segments of the air passages when normal air flow is not sufficient to move secretions or stimulate the cough reflex. Chest percussion and vibration may be employed during postural drainage to loosen secretions. **OXYGEN THERAPY** is used as a supportive measure when there is decreased oxygenation of arterial blood. It can be administered to ambulatory patients being cared for at home. Blood gas analysis is an excellent guide in determining the need for initiating oxygen therapy and for monitoring dosage.

Patient Education. As with all chronic diseases that require long-term planning and management, patient education is of primary importance in successful execution of the plan. Each of the measures previously described involves instruction of the patient and family, particularly when care is carried out on an outpatient basis. The patient should be told *why* it is necessary to stop smoking, avoid other irritating inhalants, carry out good health practices, take medication only as prescribed, and faithfully perform techniques to improve ventilation. Those patients who follow the exercises prescribed for them often find they can lead more active lives than formerly. Exertional dyspnea becomes less severe and complications from infections caused by bacteria in secretions formerly trapped in the respiratory tract are less frequent. Active participation in a program of self-care gives these patients a sense of control and improves their self-esteem.

chronic fatigue syndrome (**chronic fatigue and immunodeficiency syndrome**) persistent debilitating fatigue of recent onset, with reduction of physical activity to less than half of usual, accompanied by some combination of muscle weakness, sore throat, mild fever, tender lymph nodes, headaches, and depression, with the symptoms not attributable to any other known causes. Its nature is controversial; viral infection (including Epstein-Barr virus and human herpesvirus-6) may be associated with it, but no causal relationship has been demonstrated. A number of names have been used for this syndrome, including Iceland disease and benign myalgic encephalomyelitis.

chronic granulomatous disease chronic suppurative lymphadenitis, eczematoid dermatitis, enlargement of the liver and spleen, and chronic pulmonary disease associated with a genetically determined defect in the intracellular bactericidal function of leukocytes.

chronic obstructive lung disease (COLD) (**chronic obstructive pulmonary disease** (COPD)) **chronic airflow limitation**.

chronic regional pain syndrome reflex sympathetic dystrophy.

COPD

Abbreviation for **chronic obstructive pulmonary disease**.

COPD **chronic obstructive pulmonary disease**.

COPD

abbr.

chronic obstructive pulmonary disease

COPD,

abbreviation for **chronic obstructive pulmonary disease**.

COPD Chronic obstructive pulmonary disease Pulmonology An umbrella term for a group of usually progressive lung disorders with overlapping signs and symptoms, including asthma, bronchiectasis, chronic bronchitis, and emphysema; COPD, usually associated with a long Hx of cigarette smoking, is the 5th most common COD–65,000 deaths/yr, US, the 3rd most common–after heart diseases and schizophrenia–cause of chronic disability of older individuals, and the most common cause of pulmonary HTN and cor pulmonale in the US; the major COPD lesions, chronic bronchitis and emphysema, commonly coexist; the former is responsible for the alveolar hypoxia, ↓ PO_2, ↑ CO_2, and ↓ pH that lead to pulmonary HTN, which is seen in 65% of ♂ at autopsy and 15% of ♀, and is due to the unopposed effect of elastases in the lungs Clinical SOB, wheezing, chronic cough Diagnosis Clinical Hx, PE, pulmonary function tests Complications Bronchitis, pneumonia, lung cancer; Pts with COPD have been divided into type A with emphysema, fancifully known as 'pink puffers' and type B with chronic bronchitis–'blue bloaters'; respiratory function and dyspnea in severe COPD may improve with theophylline, which improves respiratory-muscle function Management Bronchodilators, O_2 for advanced disease Prevention Smoking cessation, ↑ dietary n-3 polyunsaturated fatty acids may protect against COPD, possibly by interfering with the

production of inflammatory mediators, including leukotrienes, platelet-activating factor, IL-1 and TNF. See **Emphysema**.

Management of COPD

Minimize airflow restriction

Reduce production of secretions

↑ Eliminate secretion

Bronchodilatation

Sympathomimetic agents, eg inhaled β_2-adrenoreceptor agonists

Anticholinergic agents, eg ipratropium, nebulized atropine

Theophylline

Corticosteroids–maximum benefit in 1st 2 wks of therapy (NEJM 1999; 340:1941oa)

Correct 2° physiologic alterations

Hypoxemia–O_2 administration

Pulmonary hypertension and cor pulmonale

Hypercapnia

Optimize functional capacity

Exercise conditioning

Upper extremity training

Respiratory muscle training

Respiratory muscle rest

Dyspnea

Nutrition

Physical and occupational therapy

Psychosocial rehabilitation

Other issues of management

α_1-antitrypsin augmentation

Bullectomy

Lung transplantation

Antibiotics with exacerbations

Smoking cessation

COPD

Abbreviation for chronic obstructive pulmonary disease.

Chronic obstructive pulmonary disease (COPD)

A term used to describe chronic lung diseases, like chronic bronchitis, emphysema, and asthma.

Mentioned in: **Bronchitis**

chronic obstructive airway disease; COAD; chronic obstructive pulmonary disease; COPD; chronic obstructive lung disease; COLD airway dysfunction (e.g. chronic bronchitis or emphysema) in cigarette smokers, or ex-smokers; presenting as type A, 'pink puffers' (breathlessness but near normal arterial oxygen and carbon dioxide levels), or type B, 'blue bloaters' (no breathlessness, but marked arterial hypoxia, carbon dioxide retention and polycythaemia)

COPD

Abbreviation for chronic obstructive pulmonary disease.

COPD

chronic obstructive pulmonary disease (COPD).

Patient discussion about COPD

Q. Yoga for COPD? I was diagnosed with COPD two years ago, and so far I manage to keep on with my life, although I stopped my regular exercise. A friend of mine that also has COPD told me about yoga exercises for COPD patients- Does anyone here knows something about it?

A. Yoga can teach you how to breath properly, and is also a very good exercise. It's also very relaxing which is also good for you lung, and you can enjoy it. Just give it a try, but ask your physician first.

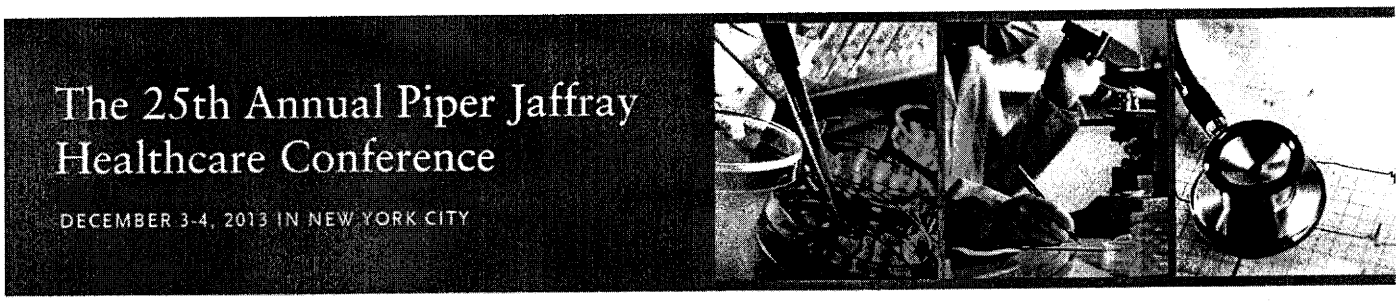
Q. (COPD)chronic obstructive pulmonary disease the main causes of?

A. Mainly smoking, although ambient air pollution and industrial exposure to dust have also been implicated as causes.

You may read more here:

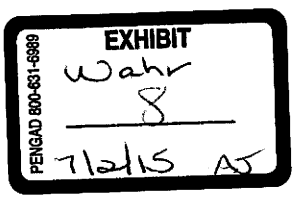
www.mayoclinic.com/health/copd/DS00916

More discussions about COPD



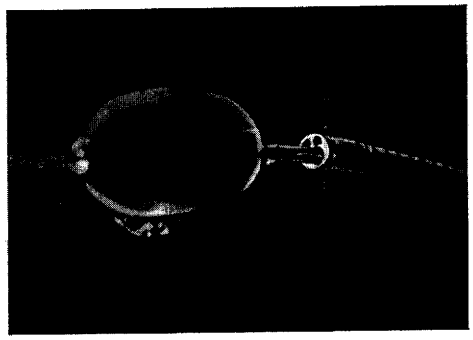
Holaira

GUIDES FOR THE JOURNEY® | PiperJaffray.



Holaira: Treatment for COPD & Asthma

- Addresses unmet clinical need
- Easy to use
- Reduce health care costs
- Massive markets



Current Status

- Novel Concept: Exceptional IP position
- Exciting human data with 12 month follow up
- Proven leadership team

Positioned to achieve meaningful value builders

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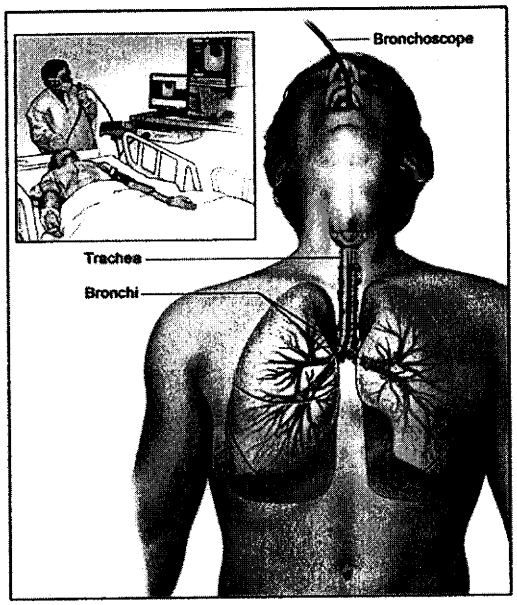
Targeted Lung Denervation (TLD)



- Employs RF energy to ablate the nerve input to the lungs which will:
  - Induce a generalized bronchodilation
  - Decrease mucus production
  - Decrease inflammation
- Outpatient procedure with sustained benefit

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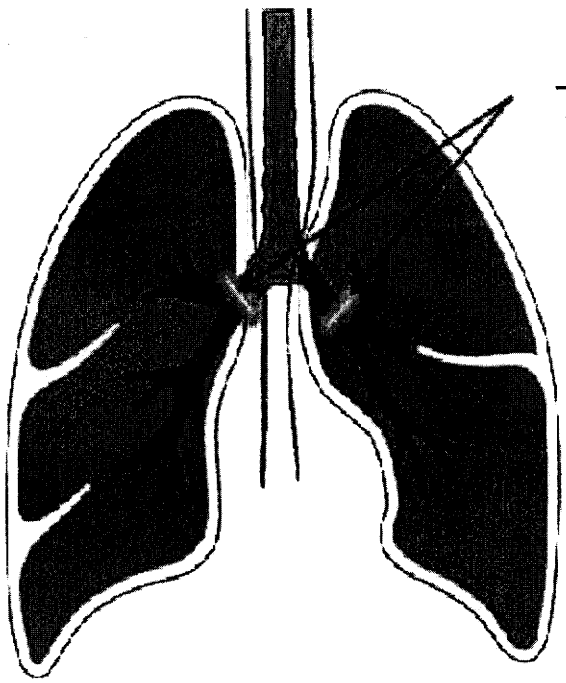
Targeted Lung Denervation (TLD)



Point of Treatment

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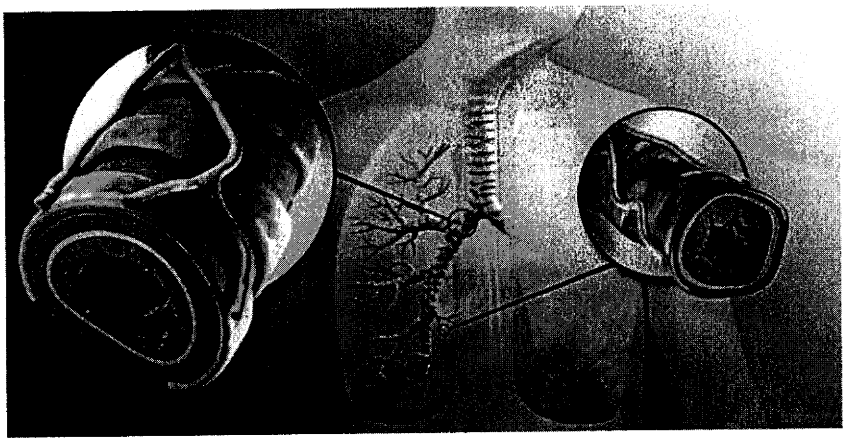
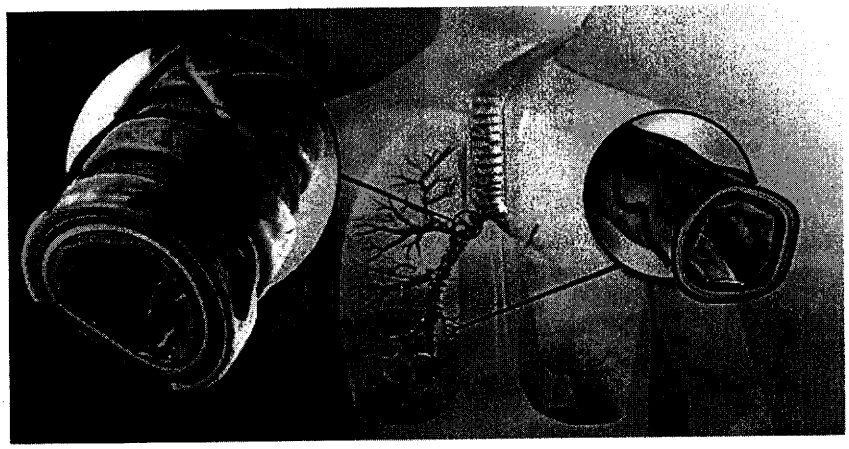
Before / After TLD Therapy



Before



After

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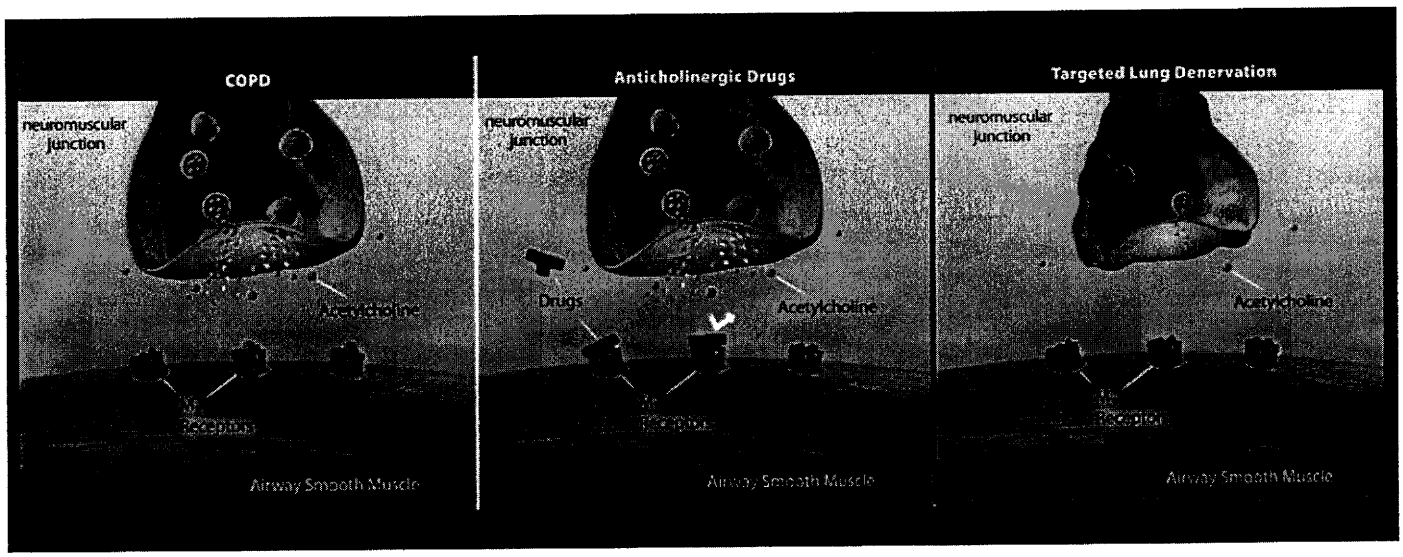
Holaira Confidential

TLD Mechanism of Action well understood



Targeted Lung Denervation reduces acetylcholine release from the nerve ending resulting in:

- Smooth muscle cell relaxation
- Sustained airway dilation

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Clinical benefits: TLD vs Drugs

	TLD	Anticholinergic Medications
Lung Distribution	Whole lung	Incomplete
Adherence	Sustained benefit	Poor
Misuse	Sustained benefit	Poor
Peak/trough variation	Stable benefit	Unavoidable
Potential synergistic effect	Yes	

- Not subject to limitations of medication but with potential for synergistic effect

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Preclinical Animal Studies

Animal Studies Summary	
• Studies performed	14
• Animals studied	94
• Airways treated	187
• Activations delivered	1099
• Days of longest follow-up	640
• Days in life	10,221

Major Findings:

- TLD disrupts bronchial nerve branches and improves airway resistance
- Effect of TLD sustained for almost 2 years
- Depth of effect tunable based on power
- Surface cooling with balloon protects airway surface and prevents stenosis

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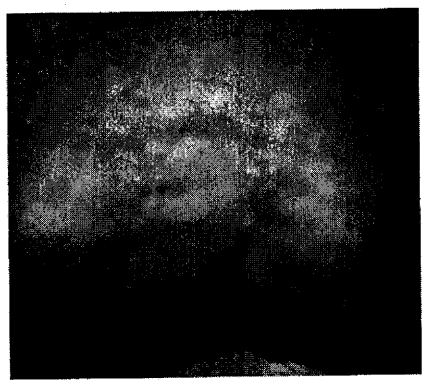
Surface Protection is key

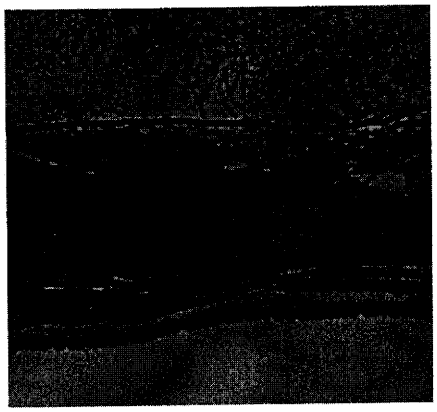
> 120 Bench-top thermal tests

Surface protection and dosing — seen and quantified

- Bench top
- Ex vivo
- In vivo



560 Ex vivo ablations



> 1300 In vivo animal histology

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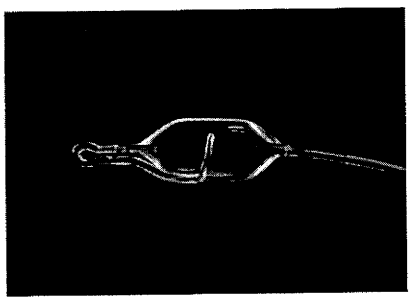
Holaira™ Lung Denervation System

Catheter Features



- Electrode requires only 4 activations
- Balloon:
  - Dual cooled
  - Compliant: "one size fits all"

- Visualization for optimal placement

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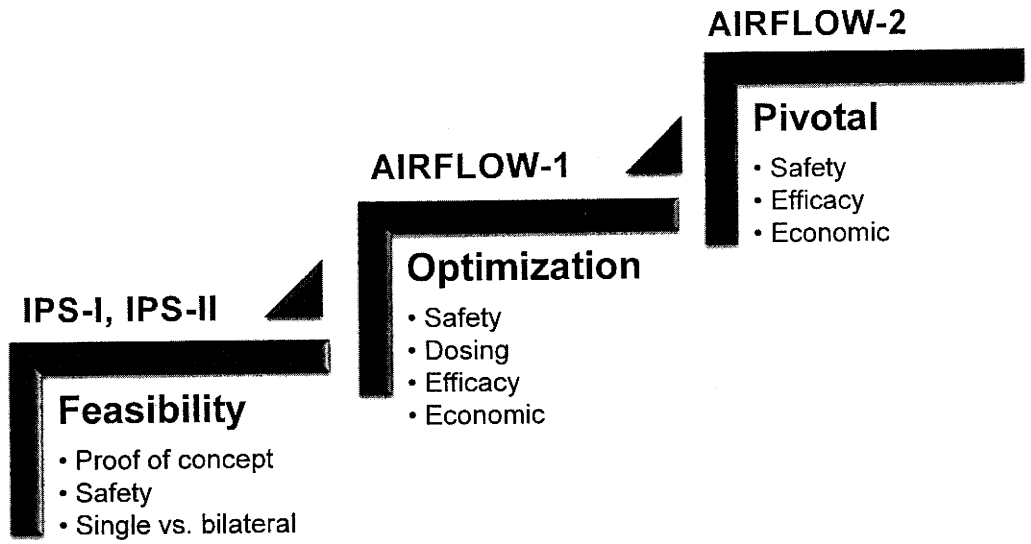
COPD Clinical Program Overview



Clinical Program Goals:

- Establish safety and efficacy
- Establish economic savings

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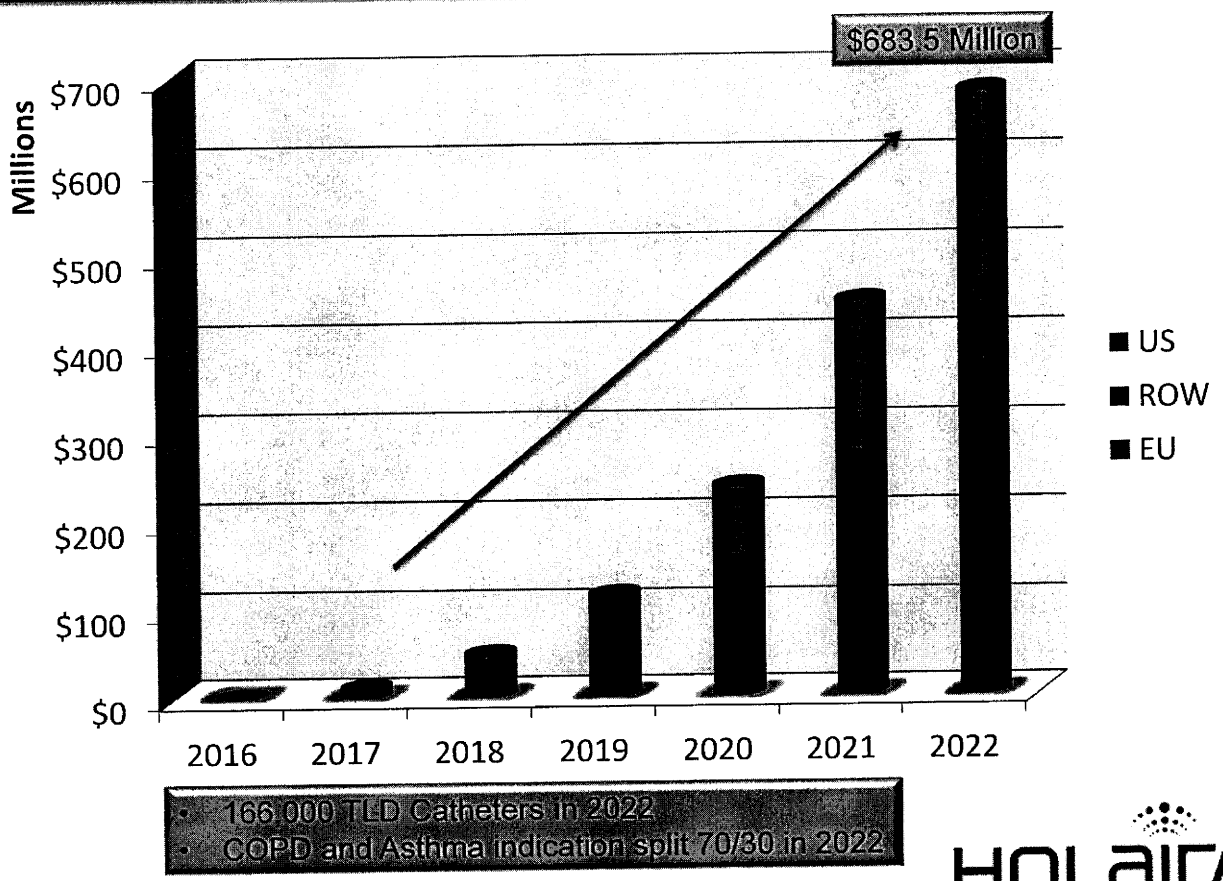
WW Revenue Projections



- 166,000 TLD Catheters in 2022
- COPD and Asthma indication split 70/30 in 2022

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Obstructive Airway Disease: Competitive Landscape

Company/Product	COPD Large Population	Asthma Intermediate Population	Emphysema Smaller Population	MOA	Ease of Use
Boehringer Ingelheim/ Spiriva	✓	✓	✓	*Temporary block of acetylcholine receptors*	Inhaler
Holaira	✓	✓	✓	***Targeted Lung Denervation*** • Sustained block of acetylcholine release • Ease of use advantage	
BSC (formerly Asthmatx)/ Alair®		✓		*Smooth muscle cell ablation*	Requires 3 outpatient procedures, > 200 total ablations in small airways
PneumRx/RePneu™ Pulmonx/Zephyr® Olympus/ IBV Valve System AerisTherapeutics/AeriSeal Uptake Medical/Intervapor™			✓	*Lung Volume Reduction*	Challenging planning required

HOLAIRA™

90+ portfolio of patents, applications and licenses

- Owned by Holaira
  - 5 US patents
  - 3 foreign patents (Europe, China, Japan)
  - 23 pending US
  - 1 pending PCT
  - 9 pending EU
  - 6 pending Japan, China
  - 9 other foreign

- Under Non-Exclusive License
  - 11 US applications pending
  - 12 US Patents
  - 2 PCT applications pending
  - 2 foreign applications pending
  - 2 foreign Patents (Europe, Australia)

- Under Exclusive License
  - 4 US Patents
  - 1 US application pending
  - 1 PCT application pending

- Investment exceeds $1.5M in external expenses
- Filings in 80% of global market

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Current Investors & Board Members

Investors

Versant Ventures

Morgenthaler Ventures

Split Rock Ventures

Advanced Technology Ventures

Board Members

Dennis Wahr M.D., President and CEO
Mike Carusi, Advanced Technology Ventures
Mark Deem, The Foundry
Kirk Nielsen, Versant Ventures
Hank Plain, Morgenthaler Ventures
Dave Stassen, Split Rock Ventures

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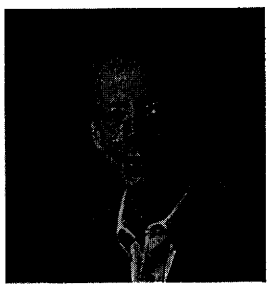
Management Team

Dennis Wahr, M.D: President & CEO

- Founder, Pres. and CEO both Lutonix & Velocimed
- Board certified Interventional Cardiologist

Martin Mayse, M.D: Founder and CTO

- Former Director Interventional Pulmonology at Wash Univ
- Board certified Pulmonologist
- Biomedical Engineer



Steve Mertens: Senior VP Operations

- Sr. VP R&D Boston Scientific
- >20yrs biomedical engineer experience
- MBA

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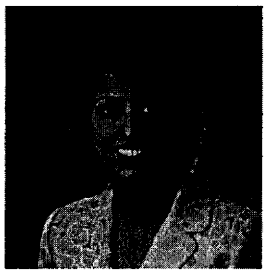
Management Team



Mahtab Fatemi, JD: Director of Regulatory Affairs

- Director Regulatory Affairs at MAP Pharmaceuticals
- >14 yrs regulatory science experience (US RAC)
- Masters Degree Science, JD Degree, State Bar of California

Kari Kubesh: CFO

- VP Finance at Lutonix
- CPA, >17yrs finance experience, public and private companies
- >10 years venture capital backed medical device companies

Jim Pavliska: VP Clinical

- Clinical Director Lutonix and Velocimed
- >15 yrs clinical research experience
- Managed > 12 US and International Clinical trials

HOLAIRA™

Series D Financing Highlights

- Amount
  - $40 million
  - Finances company through December 2016
  - Full Insider participation
- Milestones Through 2016
  - Clinical
    - COPD:
      - 12 month data from Phase II randomized study
      - 3 yr data from feasibility studies
      - IDE for US Pivotal Trial
    - Asthma
      - 6 month data from asthma feasibility study
  - Dominant position in new field of pulmonary denervation
    - Exceptional IP portfolio
    - Multiple year first mover access to US markets
  - OUS Revenue

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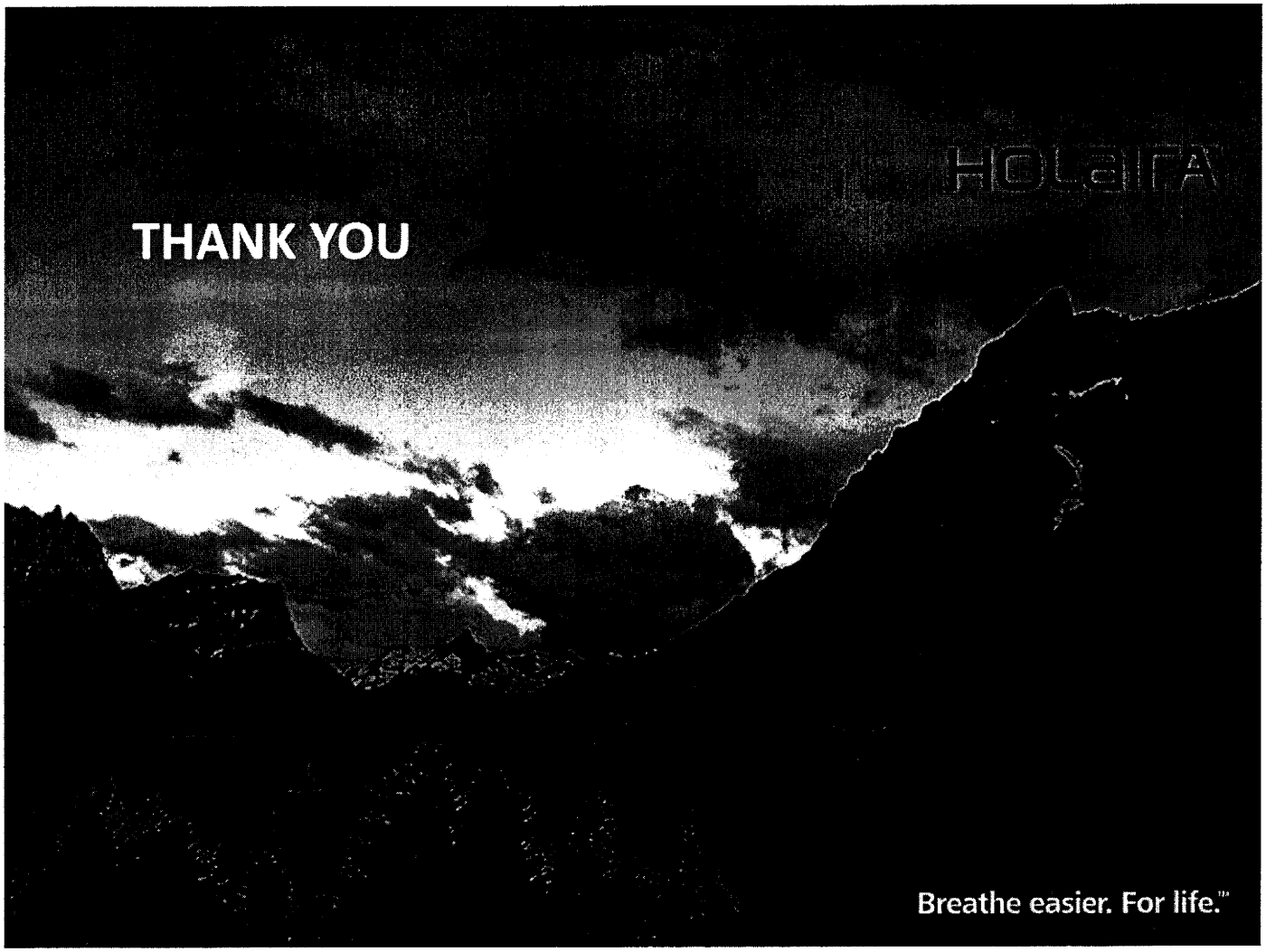
HOLAIRA
THANK YOU
Breathe easier. For life.™

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No.: 85/806,379
Filed: December 19, 2012
For the mark: HOLAIRA
Published in the *Trademark Official Gazette* on December 3, 2013

Boston Scientific Corporation and
Asthmatx, Inc.

Opposers,

v.

Holaira, Inc.

Applicant.

Opposition No. 91215699

AFFIDAVIT OF SERVICE
BY UNITED STATES MAIL

STATE OF MINNESOTA)
) *ss.*
COUNTY OF HENNEPIN)

Debra Peterfeso, being first duly sworn upon oath, states that on July 28, 2015, she served the attached:

1. CD with the deposition transcript of Dr. Dennis Wahr, Exhibits 1-9, and 11; and
2. Errata sheet of Dr. Dennis Wahr,

upon the within named counsel by United States Mail, using an envelope addressed as set forth below, with postage prepaid, and depositing the same in the United States Mail at Minneapolis, Minnesota:

Timothy D. Sitzmann, Esq.
Stephen R. Baird, Esq
Bradley J. Walz, Esq.
Winthrop & Weinstine
Capella Tower, Suite 3500
225 South Sixth Street
Minneapolis, MN 55402-4629

Attorneys for Opposers

DEBRA PETERFESO

Subscribed and sworn to before
this 28th day of July, 2015

Notary Public – Minnesota
My Commission Expires Jan. 31, 2020

JULIE ANN ANDERSON
Notary Public-Minnesota
My Commission Expires Jan 31, 2020

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AFFIDAVIT OF SERVICE
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STATE OF MINNESOTA)
) *ss.*
COUNTY OF HENNEPIN)

Debra Peterfeso, being first duly sworn upon oath, states that on November 16, 2015, she served the attached:

1. CD with deposition transcripts of Dr. Dennis Wahr (redacted and unredacted versions), Exhibits 1-9, and 11; and

2. Signed errata sheet of Dr. Dennis Wahr,

upon the within named counsel by United States Mail, using an envelope addressed as set forth below, with postage prepaid, and depositing the same in the United States Mail at Minneapolis, Minnesota:

Timothy D. Sitzmann, Esq.
Stephen R. Baird, Esq
Bradley J. Walz, Esq.
Winthrop & Weinstine
Capella Tower, Suite 3500
225 South Sixth Street
Minneapolis, MN 55402-4629

Attorneys for Opposers

DEBRA PETERFESO

Subscribed and sworn to before
this 16th day of November, 2015

Notary Public – Minnesota
My Commission Expires Jan. 31, 2020

JULIE ANN ANDERSON
Notary Public-Minnesota
My Commission Expires Jan 31, 2020